UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 11344 / December 16, 2024

SECURITIES EXCHANGE ACT OF 1934
Release No. 101931 / December 16, 2024

ACCOUNTING AND AUDITING ENFORCEMENT
Release No. 4547 / December 16, 2024

ADMINISTRATIVE PROCEEDING
File No. 3-22361

In the Matter of **BECTON, DICKINSON AND COMPANY,** **Respondent.**	**ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933 AND SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER**

I.

The Securities and Exchange Commission ("Commission" or "SEC") deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 ("Securities Act") and Section 21C of the Securities Exchange Act of 1934 ("Exchange Act") against Becton, Dickinson and Company ("BD" or "Respondent").

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the "Offer") which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission's jurisdiction over Respondent and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 8A of the Securities Act of 1933 and Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order ("Order"), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds[1] that:

Summary

1. This matter involves Becton Dickinson's repeated misrepresentations to investors regarding the risks it was taking in selling one of its most important products. From 2016 to early 2020, BD understood its Alaris infusion pump, whose sales contributed about 10% of BD's profits, required new regulatory clearance from the FDA to address historical changes to the device and to fix multiple software flaws that posed safety risks to patients. BD misrepresented these risks and failed to disclose the risk that the FDA would prohibit sales of Alaris until the company obtained new clearance and fixed its software. BD also overstated its income by failing to properly account for the costs of fixing the device.

2. In 2016, BD's regulatory experts determined that Alaris required new clearance from the FDA because of cumulative historical changes made to the device since its last regulatory clearance. In June 2016, BD began work internally to seek this clearance. Within several months, however, BD realized it was unable at that time to give the FDA information it would require to clear the device. So BD decided to change course. Instead, BD sought FDA clearance only for certain *new* features it wanted to add to Alaris in the future. However, even for this substantially narrowed submission, BD could not then give the FDA the information it needed for clearance. BD withdrew that application in June 2018 and advised the FDA it would work on a new submission. Nevertheless, BD continued to sell Alaris until 2020 while misleading investors about the company's regulatory compliance and without informing investors of the material risk that the FDA would prohibit BD from continuing to sell the device without the necessary clearance.

3. In FY2019 and FY2020, BD also materially misled investors and failed to make required disclosures about the increased risk that the FDA would prohibit sales of Alaris in light of flaws in the device's software that presented risks to patient safety. One involved the pump's low battery alarm, which was intended, but sometimes failed, to alert clinicians that Alaris was on the verge of shutting down during infusions if the device was not plugged in. Another involved error codes the device would generate in certain circumstances that delayed the start of infusions. By 2018, BD had received reports that there had been over 30 deaths or serious injuries potentially associated with these issues.[2]

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[1] The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

[2] Further investigation ultimately determined in 2020 that these issues were potentially associated with 24 serious injuries, but no deaths. In this time period, about 2 million Alaris pumps were used to deliver approximately 2.7 billion infusions to patients.

4. By January 2019, BD had identified over 25 additional flaws in Alaris's software that the company's experts categorized as presenting risks of the greatest potential harm to patients. BD did not, however, fix any of these flaws or inform investors of the heightened risk that the FDA would limit BD's ability to continue selling Alaris in light of these issues.

5. By this point, it was probable that BD would need to conduct a recall to fix Alaris. However, BD failed to comply with Generally Accepted Accounting Principles by not disclosing or properly accounting for these recall costs.

6. In October 2019, after the FDA[3] raised new concerns about Alaris's alarms, BD proposed a plan to the agency for fixing all of the software issues. In doing so, BD informed the FDA for the first time about the additional flaws it had found, including those categorized as presenting risks of the greatest potential harm to patients, which by then totaled 37. BD asked the FDA to allow the company to continue selling Alaris while it worked on addressing these issues over time. BD proposed to do this by fixing the issues with a new software version while deferring the regulatory clearance process it had tried and failed to complete previously.

7. On October 31, 2019, the FDA rejected BD's proposal, warning BD it was putting a "violative" device into the market with "defects and safety issues." The FDA informed BD that continuing to sell Alaris was "problematic" and "not an acceptable way to proceed." The FDA said, "These issues cannot be propagated in current manufacturing products. We cannot allow that to happen." The FDA added that the changes BD had proposed required regulatory clearance, and that the devices already in medical facilities needed to be recalled and remediated more quickly than BD had proposed.

8. BD understood it needed to stop selling new Alaris units until it addressed the FDA's concerns. It told the agency it would develop a new plan to fix the software issues. Immediately following this meeting, BD ceased shipping Alaris.

9. Within a few days, however, BD's then-senior management, in consultation with multiple attorneys, senior internal experts, and executives in various roles, agreed to a different plan proposed by the Alaris team that was similar to the one the FDA had already rejected: BD would, within three months, resume shipping Alaris with a new software version but without first completing the regulatory clearance process. Notwithstanding the concerns raised by the FDA several days prior, BD's plan assumed the FDA would exercise its enforcement discretion to allow BD to make changes to Alaris's software that otherwise required prior FDA clearance so that BD could resume selling the device with new software that fixed all of the issues presenting risks of the greatest potential harm.

[3] The FDA communications discussed in this Order refer to those made by and to the FDA team directly responsible for overseeing Alaris's compliance with regulatory requirements and were not binding on the agency.

10. On November 5, 2019, BD held an earnings call in which it told investors it was pausing Alaris shipments during its first fiscal quarter to make software "upgrades" to the device. On that call and in a concurrent Form 8-K, BD issued earnings and revenue forecasts that assumed the company would recoup in the remainder of FY2020 most of the sales it would not make during this pause. BD's statements materially misled investors about Alaris's regulatory status and the reliability of its forecasts because they implied the company was merely enhancing the device and were based on the company's undisclosed conjecture that the FDA would reverse course and allow BD to continue selling Alaris without clearance.

11. During this call and in the Form 8-K, BD also overstated its Q4 FY2019 operating income.[4] By this point, BD estimated the Alaris recall would cost the company $50 million. Yet it did not reserve for these costs as GAAP required. BD's failure to record the costs in Q4 FY2019 resulted in BD overstating its operating income for that quarter by 82%.

12. Later in November 2019, BD filed a Form 10-K that included various statements regarding the regulatory status of Alaris and the company's interactions with the FDA. These statements continued to mislead investors about Alaris and BD's ability to continue selling the device without new regulatory clearance.

13. In that filing, BD also materially misstated its financial results by again failing to record the estimated costs of remediating and recalling Alaris—this time overstating its FY2019 annual income before taxes by over 5%.

14. BD made additional misrepresentations to investors regarding Alaris over the following two months. At a widely attended healthcare investor conference in November 2019, BD again said it was "upgrading" Alaris and reaffirmed its previously issued earnings and revenue guidance. In December 2019, BD told participants at another investor conference it believed Alaris would continue to take market share from its competitors, and that the pause in sales would be short-lived. In neither case did BD inform investors that it had ceased shipping Alaris to address concerns raised by the FDA about the device, or that its forecasts depended on the FDA allowing the company to resume sales.

15. In December 2019, BD finalized the interim software version it had been developing and resumed selling Alaris without receiving FDA concurrence. At another investor conference in January 2020, BD told investors Alaris sales had resumed and reaffirmed its 2020 revenue forecast. BD did not, however, inform investors of the material fact that its forecast hinged on its assumption that the FDA would allow BD to continue selling the device without new regulatory clearance.

16. When the FDA learned in mid-January 2020 that BD had resumed shipping Alaris, it warned the company that its decision to resume sales was "misaligned with our previous

[4] BD's fiscal year end is September 30.

conversations regarding your software issues and our mutual agreement that your firm should not be distributing devices to new customers."

17. On January 23, BD again stopped shipping Alaris. BD did not know how long this "ship hold" would last, but understood it would likely have a substantially negative impact on the company's revenue in FY2020. Nevertheless, during its January 28 annual shareholders' meeting, BD again reaffirmed the FY2020 revenue forecasts that assumed the company would continue selling Alaris without limitation in FY2020.

18. In February 2020, BD informed investors it had ceased shipping Alaris to new customers and would not fully resume selling the device until it obtained clearance from the FDA. That announcement led to a 12% decline in the company's share price. Following the call, one analyst texted a senior member of BD's investor relations group, "I just can't even . . . I do not understand what happened here. 10 days ago we heard everything in pumps was ok and back on market and better than expected . . . I'm stunned and have a lot of angry people with pitchforks."

Respondent

19. **Becton, Dickinson and Company** is a New Jersey corporation headquartered in Franklin Lakes, New Jersey. BD is a global medical technology company that develops, manufactures, and sells medical supplies and devices. BD's stock is registered with the Commission pursuant to Exchange Act Section 12(b) and trades on the New York Stock Exchange. BD files periodic reports, including Forms 10-K and 10-Q, with the Commission pursuant to Section 13(a) of the Exchange Act and related rules thereunder.

Background

20. BD's Alaris infusion pump delivers fluids, medications, and blood to patients in hospitals throughout the United States. Alaris was a highly profitable and important product for BD that contributed a material portion of BD's total operating income in FY2019 and early FY2020, when the violations described below occurred.

21. Infusion pumps like Alaris are Class II medical devices that present moderate to high risk to patients. Section 510(k) of the Food, Drug and Cosmetic Act requires manufacturers of such devices to obtain FDA "clearance" before they can be legally marketed and sold in the U.S. To obtain this clearance, a manufacturer must demonstrate to the FDA that the device is safe and effective through a "510(k)" submission.

22. Manufacturers often make changes to medical devices after obtaining 510(k) clearance. If a manufacturer makes a modification that could significantly affect a device's safety or effectiveness—or if a manufacturer has made multiple modifications at once or over time that cumulatively could have such an effect—new 510(k) clearance from the FDA is required to

continue selling the device. However the FDA may exercise "enforcement discretion" not to bring an enforcement action for devices that require new 510(k) clearance but continue to be sold.[5]

BD's Decision Not to Obtain New 510(k) Clearance for Alaris

23. In 2016, BD's regulatory experts within the business unit responsible for the manufacture and sale of Alaris determined that because of cumulative changes made over time to Alaris's software, Alaris needed new 510(k) clearance. In June 2016, the company began working on a 510(k) submission that would cover these changes. Soon after beginning this work, however, the Alaris team realized it did not have readily available the data and documentation the FDA would require to obtain new 510(k) clearance for those historical changes.[6]

24. At that time, the Alaris team was developing new features to include in Alaris. Concerned that generating the data and documentation necessary for new 510(k) clearance would delay the release of the new features and disadvantage its competitive position, the Alaris team changed course. Rather than seek new FDA clearance for the cumulative historical changes it had made to Alaris, the Alaris team decided it would instead seek clearance for only certain *new* features it wanted to commercialize quickly.

25. After BD filed this narrowed 510(k) in October 2017, the FDA notified BD that its submission was inadequate. The FDA informed BD that to begin its substantive review, the company would need to provide, among other things, information concerning previous changes to Alaris's software, the requisite data to support those changes, and BD's rationale for not submitting a 510(k) application to cover the prior changes.

26. Because BD's data and documentation about the previous changes to Alaris was incomplete, it could not timely provide the FDA the information it requested. BD believed pushing forward with this 510(k) application posed a "High Probability of Regulatory / Compliance Risk," which included, among other things, the FDA determining Alaris was "adulterated," meaning out of compliance and in need of a new 510(k) clearance because of cumulative historical changes to the device.

27. BD withdrew this application in June 2018. The Alaris team indicated to the FDA that it would work to pursue a new 510(k) submission, including for cumulative historical changes—but without informing the agency that it had previously determined those changes necessitated new regulatory clearance. BD continued selling Alaris nonetheless.

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[5] A manufacturer may ask the FDA for a determination that the agency would not require it to stop sales of a product that requires new 510(k) clearance. The FDA exercises this enforcement discretion from time to time.

[6] BD's subsidiary responsible for Alaris ("CFN 303") had significant gaps in its data about Alaris's software development. For example, it lacked information the FDA required for new 510(k) clearance about how the software had changed over time.

28. BD knew or should have known this presented heightened risk to the company. When BD acquired the Alaris product line in 2015, Alaris was (and remains) subject to a preexisting consent decree with the FDA that resulted from longstanding compliance and safety issues with Alaris.[7] The consent decree subjects BD's subsidiary responsible for Alaris to heightened FDA scrutiny concerning its infusion pumps and gives the FDA enhanced authority to take unilateral actions for violations of FDA rules, including limiting its sales of Alaris or even prohibiting sales of the device. SEC disclosure rules required BD to disclose to investors the material uncertainty that the FDA would prohibit BD from continuing to sell Alaris without new FDA clearance.[8] However BD did not do so.

29. To the contrary, BD materially misled investors about the company's regulatory compliance risks relating to Alaris. In FY2019, BD disclosed to investors in its periodic reports that the consent decree gave the FDA authority to stop the company from continuing to sell Alaris "in the event of any violations in the future." And in its annual report during this period, BD stated that it had "made substantial progress in its compliance efforts" in connection with the consent decree. These disclosures were misleading given that (i) BD had not obtained the new 510(k) clearance its Alaris team had concluded was required and (ii) the company was unlikely to obtain such clearance in the near future.

30. By December 2018, numerous members of BD's then-executive leadership knew or should have known of significant deficiencies in how the company's business unit responsible for Alaris had been managing Alaris's regulatory requirements. They were informed that the business unit's regulatory experts had concluded in 2016 that new 510(k) clearance was needed for past changes to Alaris, that the business unit had a historical strategy of avoiding FDA engagement and 510(k)s, that there was a need for additional training regarding the quality system relating to Alaris,[9] that the withdrawn submission for new 510(k) clearance had been driven by business

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[7] The consent decree was first entered into in 2007, following safety issues in an earlier version of the Alaris infusion pump that was not manufactured by BD. Starting in 2009, Alaris was manufactured and sold by CFN 303, which BD acquired in 2015.

[8] *See* 17 CFR § 229.303 (Regulation S-K Item 303, Management's discussion and analysis of financial condition and results of operations, including description of known trends and uncertainties that have had or are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations). By no later than January 2019, the risk that the FDA would restrict BD's ability to sell Alaris was a known uncertainty that would have such a material unfavorable impact if it came to fruition. However, BD did not conduct the requisite analyses to determine that no disclosure was required. Accordingly, disclosure was required in BD's periodic filings during its FY2019. *See* Management's Discussion and Analysis of Financial Condition and Results of Operations, Exchange Act Release No. 6835, 43 S.E.C. Docket 1330, 1989 WL 1092885, at *6 (May 18, 1989).

[9] FDA rules require medical device manufacturers to "establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications." FDA, *Quality System (QS) Regulation/Medical Device Current Good Manufacturing Practices (CGMP)*, https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp.

decisions instead of regulatory strategy, and that there was a lack of internal transparency and a lack of respect for the regulatory experts within the business unit.

Misrepresentations Relating to Risks in Alaris's Software

31. Postponing a new 510(k) submission for the cumulative changes to Alaris had additional consequences beyond the heightened risk that the FDA could prohibit BD from continuing to sell the device. Obtaining clearance would have allowed BD to update Alaris's software and fix over 140 software flaws it had found. These issues had varying degrees of severity and risk. BD categorized over 15 of them as presenting risks of the greatest potential harm to patients.

32. One of these flaws involved Alaris's low battery alarm. This issue could cause Alaris, if not plugged in, to shut down when its battery was depleted without warning to the clinician. In November 2016, BD's regulatory experts planned to address this issue by modifying Alaris's software. But this fix required new 510(k) clearance before it could be implemented. That month, BD issued a recall notification informing clinicians using Alaris of the issue and ways to mitigate it and prepared a software update to fix it. This update was included in the software for which BD sought 510(k) clearance in 2017, but because BD withdrew that application in 2018, it did not fix this the flaw in units it had already sold or in new units it was selling.

33. Another issue related to a "system error code" Alaris would spontaneously generate in certain circumstances. This could interrupt or delay the start of infusions, posing an additional safety risk to patients. In June 2017, BD issued a recall notification informing clinicians of the issue and ways to mitigate it, but again, the company did not fix the software because it had withdrawn its 510(k) application in 2018. This issue therefore also persisted in devices BD had already sold and in new devices the company was continuing to sell.

34. By the end of 2018, BD had received reports of over 30 serious injuries or deaths potentially associated with the low battery alarm and system error code issues.[10]

35. Over time, BD learned of more issues with Alaris's software. By January 2019, BD was tracking over 160. By August 2019, the number had surpassed 200. Of these, BD's experts categorized over 25 as presenting risks of the greatest potential harm to patients. Though BD had told the FDA about the low battery alarm and system error code issues, it did not inform the agency of the other issues it was tracking until October 2019.

36. In August 2019, the FDA alerted BD to two additional alarm issues with Alaris that presented potential safety risks. The agency informed BD that Alaris's alarms for notifying

[10] As noted above, these reports led BD to conduct risk evaluations and make certain associated field communications. BD subsequently investigated these reports further. By February 2020, the company determined these issues were potentially associated with 24 serious injuries, but no deaths. In this time period, about 2 million Alaris pumps were used to deliver approximately 2.7 billion infusions to patients.

clinicians that infusions had ended were not sufficiently audible and should be designated as "high priority" rather than "medium priority." The FDA told BD this "alarm prioritization" issue posed safety risks because clinicians may not immediately respond to medium or low priority alarms, and when the delivery of critical medication stops, a clinician's unresponsiveness could lead to a patient's death. The FDA told BD to prioritize addressing this issue on an expedited basis.[11]

37. Though SEC disclosure rules required BD to inform investors in its periodic reports that these software issues increased the risk of regulatory action by the FDA to limit BD's ability to sell Alaris,[12] BD did not do so.

38. To the contrary, BD misled investors by giving them a materially incomplete view of the potential for recalls of its products. From 2016 to 2020, BD's annual and quarterly filings on Forms 10-K and 10-Q made generic disclosures relating to the possibility of recalls, regulatory action, loss of sales, and injuries or other adverse events due to potential product defects or safety concerns.[13] By no later than FY2019, BD's disclosures were materially misleading. They presented such events as contingent or merely possible while omitting that BD was aware of multiple issues with one of its most important products that created a heightened risk the FDA would take regulatory action to limit BD's ability to continue selling the device. Moreover, in November 2018, BD had explicitly committed to the FDA that it would recall Alaris to remediate the low battery alarm issue.

39. BD also failed to properly account for the costs of fixing these software issues. By November 2018, it was probable that fixing devices it had already sold would require BD to send technicians to medical facilities using Alaris to update the device's software. Generally Accepted Accounting Principles required BD to record or otherwise disclose its expected costs to implement these fixes.[14] BD did not do so.

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[11] The FDA explained to BD that the only other pump manufacturer that had a similar issue had already undertaken a Class I recall. Such a recall reflects the highest degree of health hazard because it involves a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

[12] *See supra* note 8.

[13] BD's Forms 10-K, in describing a risk factor concerning defects or quality issues, state: "Manufacturing or design defects . . . can lead to injury or other serious adverse events. These events could lead to recalls . . . and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs and lost sales and customers . . . as well as negative publicity and damage to our reputation that could reduce future demand for our products. . . . In some circumstances, such adverse events could also cause delays in regulatory approval of new products." BD's Forms 10-Q referred readers to these risk factors.

[14] GAAP Accounting Standards Codification (ASC) Subtopic 450 requires accrual and disclosure of material loss contingencies that are probable and reasonably estimable. A loss contingency is probable when the future event is likely to occur. BD failed to comply with GAAP with respect to its annual and quarterly periodic reports for FY2019. The company ultimately disclosed and recorded a reserve for these recall costs in Q1 FY2020.

BD's Proposal to Fix Alaris's Software Before 510(k) Clearance

40. After the FDA notified BD that it needed to fix Alaris's alarm prioritization issue, BD told the FDA it would submit a proposal to the agency that would address that issue as part of a plan the company had been discussing with the FDA since November 2018 to fix Alaris's low battery alarm.

41. BD presented its proposal in October 2019. In it, BD revealed to the FDA that Alaris had hundreds of other software flaws, including what by then were 37 that BD categorized as presenting risks of the greatest potential harm to patients. BD proposed to develop and release new software for Alaris within several months that would fix most of these issues while it worked on preparing a submission for new 510(k) clearance.[15]

42. As for the two million Alaris pumps being used in medical facilities across the country, BD proposed to recall those devices by sending technicians to remediate their software over a three-and-a-half-year period.

43. BD acknowledged to the FDA that Alaris required new 510(k) clearance for some of these fixes and said it would prepare a filing to cover them, as well as historical cumulative changes made to the device. But it told the FDA it did not expect to be able to file the 510(k) submission for over a year, until late 2020 or early 2021. In effect, BD was proposing that the agency exercise enforcement discretion to allow the company to continue selling Alaris with the new changes, while the company worked on a 510(k) filing for a year or more.

The FDA's Rejection of BD's Proposal

44. On October 31, 2019, the FDA's team responsible for overseeing Alaris's compliance with FDA rules firmly rejected BD's proposal. Concerned by the number of software issues, they warned BD it was putting a "violative" device into the market with "defects and safety issues" and that continuing to sell Alaris was "problematic" and "not an acceptable way to proceed." The FDA team said, "These issues cannot be propagated in current manufacturing products. We cannot allow that to happen."

45. The FDA team also told BD its proposed three-and-a-half-year timeline to fix the Alaris devices already in medical facilities was "unacceptable" and would need to happen more quickly.

46. BD asked the FDA whether it could submit a limited 510(k) submission in the near term that would cover only the most significant safety fixes, and leave for later a comprehensive 510(k) application for the remaining software issues and the historical changes it had made to

[15] BD had internally assessed that Alaris was safe for use even with the software flaws and shared this view with the FDA during the meeting. The FDA did not agree with BD's methodology concerning the risk assessment.

Alaris. The FDA team rejected this too, telling BD, "[w]e cannot clear the device piecemeal since the agency is aware of other safety issues."

47. To understand how rapidly BD could remediate the software issues in already-sold devices in the field, the FDA team asked BD for a timeline to fix software issues that did not require regulatory clearance. The FDA also asked BD for a timeline for fixing issues that did require clearance, in the event the agency allowed BD to make such fixes to devices it had already sold before the company obtained new 510(k) clearance. Though the FDA told BD "there are issues that BD can take action [on] now in the interim," the agency did not indicate any such fixes would be sufficient for BD to resume normal sales of Alaris before it obtained new 510(k) clearance.

48. BD understood from the October 31 meeting that the FDA team believed BD should stop selling the current version of Alaris.[16] BD told the FDA it would develop and propose a revised plan to fix the issues. Immediately afterwards, BD put Alaris on a "ship hold" to stop further sales of the device while it worked to address the FDA's questions and concerns.

49. Various BD internal experts responsible for regulatory affairs and the quality of its products—both at the corporate level and in the BD business unit that manufactured and sold Alaris—testified they had no idea how long the ship hold would last when it was implemented. Indeed, the BD regulatory expert responsible for Alaris who participated in the October 31 FDA meeting told at least one colleague that they believed the FDA would not allow BD to resume shipping Alaris until the company obtained new 510(k) clearance for the device.

50. BD's October 31 meeting with the FDA team occurred five days before the company's scheduled Q4 FY2019 earnings call on November 5, 2019. On November 4, one senior executive asked a senior member of BD's investor relations group, "[a]ny thought to delay earnings? That would prob cause hysteria?"

BD's Risky Plan to Resume Shipping Alaris Without New 510(k) Clearance

51. On November 4, 2019, in preparation for the earnings call the next day, BD's then-senior management, in consultation with company lawyers, senior internal experts, and executives in various roles—but not the regulatory expert from the business unit responsible for Alaris—agreed to proceed with a plan proposed by certain members of the Alaris team that was similar to the one the team had proposed to the FDA and that the FDA had rejected: BD would, within three months, resume shipping Alaris with a new software version but without first completing the regulatory clearance process. Notwithstanding the concerns raised by the FDA several days prior, BD's plan assumed the FDA would exercise its enforcement discretion to allow BD to make changes to Alaris's software that otherwise required prior 510(k) clearance so that BD could

[16] BD's notes of the meeting reflect the company's regulatory expert responsible for Alaris acknowledging to the FDA, "we understand you asked for a ship hold." As discussed below, in January 2020, the FDA described one outcome of the meeting as reaching a "mutual agreement that your firm should not be distributing devices to new customers."

resume selling the device with new software that fixed all of the issues presenting risks of the greatest potential harm.

52. Because BD expected this software fix to be developed within three months, it expected this plan would limit the revenue impact of the ship hold to just the first fiscal quarter and allow the company to recoup most of that forgone revenue during the remainder of FY2020.

BD's November 2019 Misrepresentations to Investors

53. Having adopted that plan, on its November 5, 2019 earnings call, BD told investors certain revenue would shift from Q1 FY2020 to the rest of the fiscal year because it "expected to move the timing" of Alaris sales to make "some improvements" to the device as part of BD's process and strategy to "continually iterate and make enhancements to the platform." BD said it was "in discussions with the FDA about the timing" of the "upgrades" to the software's "alarm prioritization and optimization." On that call and in a concurrent Form 8-K, BD issued earnings and revenue forecasts that assumed the company would recoup most of the sales it would not make during its first quarter in the remainder of FY2020.

54. BD's statements materially misled investors about Alaris's regulatory status, and the reliability of its financial forecasts. BD's statements implied the company was merely enhancing the device. In reality, BD had stopped shipping Alaris after the FDA team responsible for overseeing the device had expressed significant concerns about its software issues and compliance and referred to the device as "violative."[17] Moreover, Alaris's software issues went significantly beyond "alarm prioritization and optimization."

55. BD's statements were also misleading by omission: they failed to inform investors that the company's ability to resume Alaris sales in FY2020 hinged on the assumption that the FDA would, despite its team's recent statements, exercise enforcement discretion to permit BD to do so. BD's statements further misled investors by omitting the substantial risk of a long-term ship hold if, as one of its key regulatory experts believed, the FDA would require BD to obtain a new 510(k) clearance to resume Alaris sales to new customers.

56. In reporting its earnings during the call and in a contemporaneous Form 8-K, BD also misled investors about its financial results. By that time, BD had estimated that recalling

[17] BD's uses of the terms "improvements," "upgrades," and "enhancements" in the earnings call were false and misleading. The fixes BD was making to Alaris's software were not "enhancements." An enhancement to a medical device is "(1) a change to improve the performance or quality of a device that is (2) *not* a change to remedy a violation" of the Food, Drug and Cosmetic Act "or associated regulations enforced by the [FDA]." FDA Center for Devices and Radiological Health, *Distinguishing Medical Device Recalls from Medical Device Enhancements* (Oct. 15, 2014), https://www.fda.gov/media/89909/download?attachment (emphasis in original). BD had begun the October 31 meeting with the FDA by referring to the company's proposed fixes for the low battery alarm issue and alarm prioritization issues as enhancements. The FDA immediately corrected BD: "Want to be clear that [the low battery alarm and alarm prioritization issues] are not software enhancements. They are all recall issues." Later in the meeting, the FDA suggested that other software issues might be as well.

Alaris to fix the software issues would cost the company $50 million. BD's failure to record these probable costs in Q4 FY2019 as GAAP required resulted in the company overstating its reported operating income for the fourth quarter of 2019 by 82%.[18]

BD Continues to Mislead Investors

57. By mid-November 2019, BD changed its plan for resuming Alaris sales. BD decided not to seek enforcement discretion from the FDA to fix all the flaws presenting risks of the greatest potential harm to patients that required prior 510(k) clearance. This would mean the new version BD was developing would exclude fixes for several software issues that the FDA had expressed significant concerns about. This made the possibility that the FDA would permit BD to fully resume Alaris sales even more remote in light of the FDA team's statements that it could not allow BD to further propagate such issues in currently manufactured products.

58. BD echoed its prior misrepresentations at an investor conference in late November 2019. BD told investors it was "upgrading some software in the pumps, and that will delay some installations and shipment into the subsequent quarters, and we anticipate getting all of that back inside of the fiscal year." BD further stated, "we posted our strongest ever revenue dollars in the [business unit responsible for Alaris] in the fourth quarter [of 2019], and we expect that momentum to continue when you look at the full year of fiscal '20."

59. BD made similar misrepresentations during another investor conference in early December 2019, stating that it believed Alaris would continue to take market share from its competitors and that the pause in sales would be short-lived.

60. In neither of these investor conferences did BD inform investors that its forecasts depended on the FDA allowing BD to resume selling Alaris with a new version of the software that did not fix all of the safety issues that the FDA team had raised significant concerns about during their October 31 meeting.

BD's Material Misrepresentations and Omissions in Its 2019 Form 10-K

61. On November 27, 2019, BD filed its FY2019 Form 10-K. As in earlier filings, this Form 10-K included several materially misleading statements concerning regulatory risks as well as the possibility of recalls, lost sales, and injuries or other adverse events due to potential product defects or safety concerns. BD presented these risks as contingent or merely possible even though it knew Alaris was on a ship hold because the FDA had told BD the device was violative, that the

[18] BD's accounting practice at that time was not to disclose or record the costs of a recall until the company had publicly announced the recall. BD erroneously believed no GAAP obligation existed before the public announcement of a recall based on interpretative guidance it found online from a "Big Four" audit firm. It was wrong for BD to narrowly rely on this guidance. In evaluating whether to record or disclose a loss from a recall, ASC 450 requires consideration of all available information to assess whether a loss was probable or reasonably possible. BD made no such assessment. BD's written policy regarding accounting for recall costs was inconsistent with GAAP for similar reasons.

FDA might require the ship hold to last until BD obtained new 510(k) clearance, that Alaris had numerous software flaws categorized as presenting risks of the greatest potential harm to patients, and that BD planned to recall Alaris.

62. Also as in earlier filings, BD failed to comply with SEC disclosure rules requiring the company to inform investors of the material uncertainty that BD might be unable to resume shipping Alaris until it had obtained new 510(k) clearance.

63. And BD again materially overstated its financial results. By the time BD filed this Form 10-K, it had updated its estimate of the remediation costs to recall Alaris to $59 million. As in its November 5, 2019 Form 8-K, BD failed to disclose and accrue these costs in its Form 10-K's financial statements as GAAP required. Had BD recorded the $59 million estimated cost in its financial statements for FY2019, its annual income before taxes would have been over 5% lower.

64. Pursuant to BD's disclosure controls and procedures, BD's Disclosure Committee, Audit Committee, outside auditor, and BD's board of directors reviewed the draft filing before it was submitted.[19] These procedures did not, however, include any review by, or consultations with, the regulatory or quality experts in the business unit who had participated in the October 31, 2019 discussions with the FDA about Alaris.

BD Resumes Shipping Alaris Without New Clearance and Continues to Mislead Investors

65. In December 2019, BD finalized the new interim software version it had been developing and resumed regular sales of Alaris with the updated software, including to new customers. BD did so without any indication from the FDA that it concurred with BD's approach.[20]

66. At a healthcare conference on January 14, 2020, BD told investors it had resumed shipping Alaris and reaffirmed the 2020 revenue guidance it had given in November. After an analyst at the conference asked BD for an update on Alaris "as you await guidance from the FDA

[19] BD's disclosure controls and procedures required Disclosure Committee members to certify, prior to the filing of any periodic report, that the report did not contain any untrue statement of material fact or omit to state a material fact. These certifications were not distributed to Disclosure Committee members in connection with the 2019 Form 10-K, and none were executed, in contravention of BD's own controls and procedures.

[20] While BD and the FDA had discussions following their October 31 meeting about the company developing a new version of its software, those discussions focused on BD's plan to "remediate all devices in the field"—i.e. to fix the pumps it had already sold. At no point during or following the October 31 meeting did the FDA indicate that it would grant BD enforcement discretion to resume regular sales of Alaris. On December 16, 2019, BD informed the FDA that it had finalized the new software and added "BD would like to initiate remediating the products in the field as soon as possible and will begin offering this new software version to all customers." In the context of their prior discussions, this only suggested that BD would offer the update to remediate devices already sold to customers rather than to resume sales of new devices.

around fixing some of the alarms," BD responded it had "[f]ully resumed shipping in the first quarter" and that the situation played out "exactly as expected."

67. BD knew or should have known these statements were materially false or misleading in multiple respects. In the context of its prior statements about Alaris, BD's statements at the conference misleadingly suggested it had fixed the Alaris alarm issues. However, the software version it developed did not include those fixes because BD had determined they required 510(k) clearance. BD's statements further suggested that BD had resumed shipping with the FDA's concurrence. This was not the case.

BD Reinstates Ship Hold But Again Misleadingly Reaffirms Prior Revenue Guidance

68. In mid-January 2020, while discussing BD's efforts to remediate Alaris devices in the field, the FDA learned BD had resumed regular sales of Alaris with the new software version that did not fix certain significant safety issues the FDA had warned the company about on October 31. The FDA team responded by telling BD they had understood from the company that it had "ceased distribution of devices to customers . . . due to the many issues that have been identified, except in the case of remediation." The FDA team further told BD that its decision to resume selling Alaris was "misaligned with our previous conversations regarding your software issues . . . and our mutual agreement that your firm should not be distributing devices to new customers."

69. BD reinstated the Alaris ship hold on January 23, 2020. Though BD did not know how long the ship hold would last, the company understood it would likely have a materially negative impact on the company's revenue in FY2020.

70. On January 28, 2020, BD held its annual shareholders meeting. Despite the Alaris team having prepared a financial forecast several days prior showing the ship hold would likely have a materially unfavorable revenue impact in FY2020, BD again reaffirmed the FY2020 revenue guidance it had originally made in November 2019 when it planned to fully resume Alaris sales after one quarter.

BD Informs Investors About Need for New 510(k) Clearance

71. On February 6, 2020, BD conducted an earnings call for Q1 FY2020. During this call, the company finally told investors about its need to obtain new 510(k) clearance for Alaris and revised its financial guidance for the full fiscal year. It told investors that until the FDA granted that clearance, it would not sell the device to new customers; sales would be limited only to cases of medical necessity to existing customers. That day, BD's share price fell by about 12%.

72. During the call, one analyst asked management "how you got caught off guard and how this went from sort of a software upgrade to something much more significant." That day, another analyst texted a senior member of BD's investor relations group, "I just can't even . . . I do not understand what happened here. 10 days ago we heard everything in pumps was ok and back

on market and better than expected . . . I'm stunned and have a lot of angry people with pitchforks."

Violations

73. As a result of the conduct described above, BD violated Sections 17(a)(2) and (a)(3) of the Securities Act, which prohibit any person from directly or indirectly obtaining money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or engaging in any transaction, practice, or course of business which operates or would operate as a fraud or deceit upon the purchaser, in the offer or sale of securities.[21]

74. BD violated Section 13(a) of the Exchange Act and Rules 13a-1, 13a-11, and 13a-13 thereunder, which require that every issuer of a security registered pursuant to Exchange Act Section 12 file with the Commission, among other things, annual, quarterly, and current reports as the Commission may require. BD also violated Rule 12b-20 of the Exchange Act, which requires an issuer to include in a statement or report filed with the Commission any information necessary to make the required statements in the filing not materially misleading.

75. BD violated Exchange Act Section 13(b)(2)(A), which requires reporting companies to make and keep books, records and accounts which, in reasonable detail, accurately and fairly reflect their transactions and dispositions of their assets. BD also violated Section 13(b)(2)(B), which requires all reporting companies to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that, among other things, transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP.

76. BD violated Exchange Act Rule 13a-15, which requires that every issuer of a security registered pursuant to Exchange Act Section 12 maintain disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e), and, for issuers required to file an annual report pursuant to Section 13(a) or 15(d) for the prior fiscal year, internal control over financial reporting as defined in Rule 13a-15(f).

Undertakings

77. Respondent has undertaken to complete the following actions:

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[21] Violations of Sections 17(a)(2) and (a)(3) of the Securities Act do not require scienter. *See Aaron v. SEC*, 446 U.S. 686, 695-96 (1980). During its FY2019 and FY2020, BD offered and sold stock to its employees through an Employee and Director Equity-Based Compensation Plan, for which a Form S-8 was filed with the Commission. The S-8 incorporated by reference all subsequent filings by BD under the Exchange Act, including the filings containing statements and omissions at issue herein.

a. Retention of Independent Compliance Consultant. Within 30 days of the issuance of this Order, Respondent shall retain the services of an Independent Compliance Consultant ("Independent Consultant") acceptable to the staff of the Commission and provide a copy of this Order to the Independent Consultant. Respondent shall provide the Commission staff with a copy of the engagement letter detailing the Independent Consultant's responsibilities, which shall include the reviews and reports to be made by the Independent Consultant as set forth in this Order. The Independent Consultant's compensation and expenses shall be borne exclusively by Respondent.

b. Independent Consultant's Reviews. Respondent shall require the Independent Consultant to:

   i. Review the company's practices and procedures relating to: its evaluation of product recalls and remediation under GAAP and its disclosure controls and procedures, including but not limited to controls and procedures relating to collection and assessment of information concerning potential risks, contingencies, operating events, trends, and uncertainties.

   ii. At the end of the review, but no later than 365 days after the entry of this Order, submit a written report to Respondent and the Commission staff that shall include a description of the review performed, the names of the individuals who performed the review, the Independent Consultant's findings and recommendations for changes or improvements to the disclosure controls, policies, and procedures, and a procedure for implementing the recommended changes and improvements.

c. Respondent shall, within 60 days of receipt of the Independent Consultant's report, adopt all recommendations contained in the report, provided, however, that within 45 days after the date of receipt of the report, Respondent shall in writing advise the Independent Consultant and the Commission staff of any recommendations that it considers to be unduly burdensome, impractical, or inappropriate. With respect to any recommendation that Respondent considers to be unduly burdensome, impractical, or inappropriate, Respondent need not adopt that recommendation at that time but Respondent shall instead propose in writing to the Independent Consultant and Commission staff an alternative policy or procedure designed to achieve the same objective or purpose as that recommended by the Independent Consultant, or a different timeline for implementation in light of the recommendation. Respondent shall attempt in good faith to reach an agreement with the Independent Consultant on any recommendations objected to by Respondent. Within 15 days after the conclusion of the discussion and evaluation by Respondent and the Independent Consultant, Respondent shall require that the Independent Consultant inform Respondent and the Commission staff in writing of the Independent Consultant's final determination concerning any recommendation. At the same time, Respondent may seek approval from the Commission staff to not adopt the recommendations that

Respondent can demonstrate to be unduly burdensome, impractical, or inappropriate. In the event that Respondent and the Independent Consultant are unable to agree on an alternative proposal within 30 days and the Commission staff does not agree that any proposed recommendations are unduly burdensome, impractical, or inappropriate, Respondent shall abide by the determinations of the Independent Consultant.

d. Within 30 days of Respondent's adoption and implementation of all of the recommendations in the Independent Consultant's report that the Independent Consultant deems appropriate, as determined pursuant to the procedures set forth herein, Respondent shall certify in writing to the Independent Consultant and the Commission staff that Respondent has adopted and implemented all recommendations in the applicable report. The Commission staff may make reasonable requests for further evidence of compliance, and Respondent agrees to provide such evidence.

e. Respondent shall cooperate fully with the Independent Consultant and shall provide the Independent Consultant with access to such of its files, books, records, and personnel as reasonably requested for the Independent Consultant's review, including access by on-site inspection. To ensure the independence of the Independent Consultant, Respondent (1) shall not have the authority to terminate the Independent Consultant or substitute another independent consultant for the initial Independent Consultant without prior written approval of the Commission staff; and (2) shall compensate the Independent Consultant and persons engaged to assist the Independent Consultant for services rendered pursuant to this Order at their reasonable and customary rates.

f. The deadlines in this Undertaking shall be counted in calendar days, except that if the last day falls on a weekend or federal holiday, the next business day shall be considered the last day.

g. For the period of engagement and for a period of two years from completion of the engagement, Respondent shall not (i) retain the Independent Consultant for any other professional services outside of the services described in this Order; (ii) enter into any other professional relationship with the Independent Consultant, including any employment, consultant, attorney-client, auditing or other professional relationship; or (iii) enter, without prior written consent of the Commission staff, into any such professional relationship with any of the Independent Consultant's present or former affiliates, employers, directors, officers, employees, or agents acting in their capacity as such.

h. Respondent shall not be in, and shall not have, an attorney-client relationship with the Independent Consultant and shall not seek to invoke the attorney-client privilege or any

other doctrine of privilege to prevent the Independent Consultant from transmitting any information, reports, or documents to the Commission.

i. The reports by the Independent Consultant will likely include confidential financial, proprietary, competitive business, or commercial information. Public disclosure of the reports could discourage cooperation, impede pending or potential government investigations, or undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof are intended to remain and shall remain non-public, except (1) pursuant to court order, (2) as agreed to by the parties in writing, (3) to the extent that the Commission determines in its sole discretion that disclosure would be in furtherance of the Commission's discharge of its duties and responsibilities, or (4) as otherwise required by law.

j. Respondent shall certify, in writing, compliance with the undertaking(s) set forth above. The certification shall identify the undertaking(s), provide written evidence of compliance in the form of a narrative, and be supported by exhibits sufficient to demonstrate compliance. The Commission staff may make reasonable requests for further evidence of compliance, and Respondent agrees to provide such evidence. The certification and supporting material shall be submitted to Pei Chung, Associate Director, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549, with a copy to the Office of Chief Counsel of the Enforcement Division, 100 F St., NE, Washington, DC 20549, no later than sixty (60) days from the date of the completion of the undertakings.

Respondent may apply to the Commission staff for an extension of the deadlines described above before their expiration, and upon a showing of good cause by the Respondent, the Commission staff may, in its sole discretion, grant such extensions for whatever time period it deems appropriate.

IV.

In view of the foregoing, the Commission deems it appropriate and in the public interest to impose the sanctions agreed to in Respondent's Offer.

Accordingly, it is hereby ORDERED that:

A. Pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, Respondent shall cease and desist from committing or causing any violations and future violations of Sections 17(a)(2) and (a)(3) of the Securities Act and Sections 13(a), 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act, and Rules 12b-20, 13a-1, 13a-11, 13a-13, and 13a-15 promulgated thereunder.

B. Respondent shall, within 10 days of the entry of this Order, pay a civil money penalty in the amount of $175,000,000 to the Securities and Exchange Commission. If timely payment is not made, additional interest shall accrue pursuant to 31 U.S.C. § 3717.

Payment must be made in one of the following ways:

(1) Respondent may transmit payment electronically to the Commission, which will provide detailed ACH transfer/Fedwire instructions upon request;

(2) Respondent may make direct payment from a bank account via Pay.gov through the SEC website at http://www.sec.gov/about/offices/ofm.htm; or

(3) Respondent may pay by certified check, bank cashier's check, or United States postal money order, made payable to the Securities and Exchange Commission and hand-delivered or mailed to:

Enterprise Services Center
Accounts Receivable Branch
HQ Bldg., Room 181, AMZ-341
6500 South MacArthur Boulevard
Oklahoma City, OK 73169

Payments by check or money order must be accompanied by a cover letter identifying BD as Respondent in these proceedings, and the file number of these proceedings; a copy of the cover letter and check or money order must be sent to Pei Chung, Associate Director, Division of Enforcement, Securities and Exchange Commission, 100 F St., NE, Washington, DC 20549.

C. Pursuant to Section 308(a) of the Sarbanes-Oxley Act of 2002, a Fair Fund is created for the penalty referenced in paragraph B above. Amounts ordered to be paid as civil money penalties pursuant to this Order shall be treated as penalties paid to the government for all purposes, including all tax purposes. To preserve the deterrent effect of the civil penalty, Respondent agrees that in any Related Investor Action, it shall not argue that it is entitled to, nor shall it benefit by, offset or reduction of any award of compensatory damages by the amount of any part of Respondent's payment of a civil penalty in this action ("Penalty Offset"). If the court in any Related Investor Action grants such a Penalty Offset, Respondent agrees that it shall, within 30 days after entry of a final order granting the Penalty Offset, notify the Commission's counsel in this action and pay the amount of the Penalty Offset to the Securities and Exchange Commission. Such a payment shall not be deemed an additional civil penalty and shall not be deemed to change the amount of the civil penalty imposed in this proceeding. For purposes of this paragraph, a "Related Investor Action" means a private damages action brought against Respondent by or on behalf of one or more investors based on substantially the same facts as alleged in the Order instituted by the Commission in this proceeding.

D. Respondent shall comply with the undertakings enumerated in paragraph 77 above.

By the Commission.

Vanessa A. Countryman
Secretary