July 21, 2023

BD Receives FDA 510(k) Clearance for Updated BD Alaris™ Infusion System

Dear Valued BD Alaris™ System Customer:

Thank you for being a loyal BD Alaris™ Infusion System customer and for your tremendous support and partnership as we navigated the BD Alaris™ Infusion System clearance with the U.S. Food and Drug Administration (FDA). **Today, we are writing to announce that we have received 510(k) clearance from the FDA for the updated BD Alaris™ Infusion System. This clearance covers updated hardware features for the Point-of-Care Unit (PCU), large volume pumps, syringe pumps, patient-controlled analgesia (PCA) pumps, respiratory monitoring modules. It also covers a new BD Alaris™ Infusion System software version, enhanced cybersecurity, and interoperability features that enable smart, connected care with the most widely used electronic medical record (EMR) systems.**

The clearance is supplemented by a comprehensive portfolio of infusion sets to be used with the BD Alaris™ Infusion System. It enables both remediation of existing devices and a return to full commercial operations for the most comprehensive infusion system available in the United States.

The updated BD Alaris™ Infusion System includes remediations for all previously announced software and hardware recalls and includes cybersecurity updates. Software v12.3 underwent extensive Human Factors testing with end users, including nurses, pharmacists and technicians, to evaluate and assess the usability of the BD Alaris™ Infusion System with Guardrails™ Suite MX and Interoperability software. With this clearance, it is the FDA's expectation that all BD Alaris™ Infusion System devices in the U.S. market will be remediated to ensure customers are using the 510(k) cleared product to deliver critical infusions to their patients. For your reference, previous recall letters can be found at https://www.bd.com/alaris-system-hardware-recall.

BD is dedicated to delivering the latest standard of patient care to our valued BD Alaris™ Infusion System customers. BD will actively engage and start working in close partnership with our customers to undertake and complete the remediation or replacement of all devices over the coming years.

BD has been proactively planning for 510(k) clearance and is fully prepared to activate our commercial and operational arms to support our customers with new device implementations, software updates, hardware remediations and interoperability implementations. Your BD Account Executive and BD Remediation Team representative will be sharing more information with you in the coming days regarding scheduling remediation.

We remain deeply committed to delivering next generation quality and compliance. These 510(k) clearances mark the next step in our journey of continuous innovation for the BD Alaris™ Infusion System, which will include filing subsequent 510(k) filings, as appropriate.

We look forward to continuing our journey with you to provide deep clinical, operational and technical expertise to remediate and deploy new systems. As always, BD's actions are guided by our commitment to patient safety and minimizing disruption of patient care.

If you have any questions regarding the products or remediation, please contact your BD Account Executive or the following support centers:

Contact	Contact Information	Areas of Support
Technical Support	Phone: 1-888-812-3229 Phone hours: 6:00am to 5:00pm PT, Monday – Friday Email: DL-US-INF-TechSupport@bd.com	Technical Questions
North America Regional Complaint Center	Phone: 1-844-823-5433 Phone hours: 8:00am to 5:00pm CT Monday – Friday Email: productcomplaints@bd.com	Product Complaints
BD Recall Support Center	Phone: 1-888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday – Friday Email: SupportCenter@bd.com	Recall Related Questions

Sincerely,

Michael Cusack
Vice President and General Manager of U.S. Region
BD Medication Management Solutions