BD Announces FDA 510(k) Submission for BD Alaris™ System

FRANKLIN LAKES, N.J., April 26, 2021 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced it has submitted a 510(k) premarket notification to the U.S. Food and Drug Administration (FDA) for the BD Alaris™ System, the most widely used infusion pump in acute care hospitals across the United States.

The 510(k) submission is intended to bring the regulatory clearance for the BD Alaris™ System up to date, implement updated features and address open recall issues, including through a new version of BD Alaris™ System software that will provide clinical, operational and cybersecurity updates.

"Today marks an important milestone in our commitment to our customers and patients and*Advancing the world of health™*," said Michael Garrison, worldwide president of Medication Management Solutions for BD. "The 510(k) submission is the first step in the review process with the FDA, and we look forward to working through the FDA review process to obtain clearance for the updated BD Alaris™ System."

The BD Alaris™ System allows clinicians to deliver medications, fluids and blood products through a single integrated platform that includes large volume pumps, syringe pumps and patient-controlled analgesia (PCA) modules for adult, pediatric and neonatal patients.

About BD
BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 70,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter @BDandCo.

Forward Looking Statements
This press release contains certain forward-looking statements regarding BD's 510(k) premarket notification to the FDA for the BD Alaris™ System. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements, and there can be no assurance that BD will obtain 510(k) clearance from the FDA for the BD Alaris™ System or as to the timing of any such clearance. Many of these risks and uncertainties are beyond the company's control, including without limitation, risks relating to regulatory clearance and market acceptance of the BD Alaris™ System, the remediation of our infusion pump business and other factors listed in our 2020 Annual Report on Form 10-K and other filings with the SEC. BD expressly disclaims any undertaking to update any forward-looking statements set forth herein to reflect events or circumstances after the date hereof, except as required by applicable laws or regulations.

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SOURCE BD (Becton, Dickinson and Company)
