Globus Medical Announces FDA 510(k) Clearance for Excelsius3D™

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Excelsius3D™ – Intelligent 3-in-1 Intraoperative Imaging System

AUDUBON, Pa., Aug. 16, 2021 (GLOBE NEWSWIRE) -- Globus Medical, Inc. (NYSE: GMED), a leading musculoskeletal solutions company, today announced that Excelsius3D™, an intelligent intraoperative 3-in-1 imaging system, has been granted 510(k) clearance by the U.S. Food and Drug Administration (FDA).

Excelsius3D™ is a 3-in-1 imaging platform that consolidates 360° cone-beam CT, fluoroscopy, and high-resolution digital radiography into one unified solution, eliminating the need for multiple imaging systems during one procedure. Precise motion, omnidirectional wheels, and intelligent maneuverability offer unmatched imaging capability. The compact footprint and elimination of a separate viewing station amplify the system's agility and efficiency. Excelsius3D™ functions as an elite, standalone imaging unit, or as an elegant extension to the Excelsius™ ecosystem.

"Excelsius3D™ underwent rigorous performance testing of various capabilities to support this 510(k) clearance, as it is our first imaging system 510(k) to be filed with the FDA's Office of In Vitro Diagnostics and Radiological Health," commented Kelly Baker, PhD, Senior Vice President, Regulatory and Clinical Affairs. "We are excited to expand into a new product space with the FDA and help bring this truly innovative system to market."

With 510(k) FDA clearance in hand, Globus Medical is ramping up production and preparing for commercial release in the fourth quarter.

Indications for Use
Excelsius3D™ is a mobile X-ray system designed for 2D fluoroscopy, 2D digital radiography, and 3D imaging of adult and pediatric patients. The system is indicated for use where a physician benefits from 2D and 3D information on anatomic structures and high contrast objects with high x-ray attenuation such as bony anatomy and metallic objects. Excelsius3D™ images are compatible with image guided systems such as ExcelsiusGPS®.

About Globus Medical, Inc.
Globus Medical, Inc. is a leading musculoskeletal solutions company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders. Additional information can be accessed at http://www.globusmedical.com.

Safe Harbor Statements
All statements included in this press release other than statements of historical fact are forward-looking statements and may be identified by their use of words such as "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect," "plan" and other similar terms. These forward-looking statements are based on our current assumptions, expectations and estimates of future events and trends. Forward-looking statements are only predictions and are subject to many risks, uncertainties and other factors that may affect our businesses and operations and could cause actual results to differ materially from those predicted. These risks and uncertainties include, but are not limited to, health epidemics, pandemics and similar outbreaks, including the COVID-19 pandemic, factors affecting our quarterly results, our ability to manage our growth, our ability to sustain our profitability, demand for our products, our ability to compete successfully (including without limitation our ability to convince surgeons to use our products and our ability to attract and retain sales and other personnel), our ability to rapidly develop and introduce new products, our ability to develop and execute on successful business strategies, our ability to comply with laws and regulations that are or may become applicable to our businesses, our ability to safeguard our intellectual property, our success in defending legal proceedings brought against us, trends in the medical device industry, general economic conditions, and other risks. For a discussion of these and other risks, uncertainties and other factors that could affect our results, you should refer to the disclosure contained in our most recent annual report on Form 10-K filed with the Securities and Exchange Commission, including the sections labeled "Risk Factors" and "Cautionary Note Concerning Forward-Looking Statements," and in our Forms 10-Q, Forms 8-K and other filings with the Securities and Exchange Commission. These documents are available at www.sec.gov. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for us to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. Forward-looking statements contained in this press release speak only as of the date of this press release. We undertake no obligation to update any forward-looking statements as a result of new information, events or circumstances or other factors arising or coming to our attention after the date hereof.

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