Globus Medical Receives FDA 510(k) Clearance for ExcelsiusFlex™ and ACTIFY™ 3D Total Knee System

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AUDUBON, Pa., July 17, 2024 (GLOBE NEWSWIRE) -- Globus Medical, Inc. (NYSE: GMED), a leading musculoskeletal solutions company, today announced it recently received 510(k) clearance by the U.S. Food and Drug Administration (FDA) for ExcelsiusFlex™ with Total Knee Arthroplasty (TKA) application. This new robotic navigation platform joins the already best-in-class Excelsius™ ecosystem, designed to offer surgeons control, resection accuracy, and procedural flexibility in Total Knee Arthroplasty. Additionally, ACTIFY™ 3D Total Knee System, the latest in implant technology that will pair with ExcelsiusFlex™, has also received 510(k) clearance.

ExcelsiusFlex™ is engineered to assist the surgeon in primary total knee arthroplasty procedures for robotically guided resections based on their implant placement planning. Multiple workflows and unrestricted jig-less resections are offered to restore control of the saw and the procedure to the surgeon. Streamlined user software is designed to enable efficient procedures.

The ACTIFY™ 3D Total Knee System is a contemporary total knee solution that is designed to pair cementless reconstruction with operative efficiency and anatomic fit. Whether through manual or robotic-assisted workflows, ACTIFY™ 3D is additive engineered to combine strength and a porous lattice interface conducive to cementless fixation. The system provides a comprehensive suite of implants and instruments to address individual surgeon preferences and varying anatomy in a diverse patient population.

“With the addition of ExcelsiusFlex™ and ACTIFY™ 3D, we look forward to introducing next generation robotic technology along with the next generation of implant technology to the orthopedic market,” commented Dan Scavilla, president and CEO of Globus Medical. “The precision, efficiency, and flexibility these systems offer will help to provide surgeons a best-in-class solution for treating patients.”

With 510(k) FDA clearances in hand, Globus Medical is ramping up production and preparing for commercial release in the near future.

Indications for Use
ExcelsiusFlex™ when used in conjunction with ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures and for spatia positioning and orientation of a tool holder to be used by surgeons for navigating and/or guiding compatible surgical instruments provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or directly acquired anatomical structures. The system is indicated to assist the surgeon in planning the position of the implant components and preparing the bony anatomy during orthopedic procedures.

The Total Knee Arthroplasty (TKA) implant systems compatible with ExcelsiusFlex™ are GENflex2™ and ACTIFY™ Total Knee Systen

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans, fluoroscopy or directly acquired anatomical structures. The system is indicated for the planning of orthopedic devices and placement of spinal and orthopedic bone screws and interbody fusion devices.

ACTIFY™ Total Knee System and ACTIFY™ 3D Total Knee System are indicated for single use only in skeletally mature individuals undergoing reconstruction of severely disabled and/or very painful joints.

ACTIFY™ Total Knee System and ACTIFY™ 3D Total Knee System are indicated for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post-traumatic degenerative problems, and revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

ACTIFY™ Total Knee System is indicated for cemented use only, except for the porous femoral component which is indicated for both cemented and uncemented use.

ACTIFY™ 3D Total Knee System is indicated for cemented and uncemented use.

About Globus Medical, Inc.
Globus Medical is a leading musculoskeletal company based in Audubon, PA, relentlessly focused on developing technologies, procedures and products that solve unmet clinical needs, promote healing in patients, and change lives around the globe. Additional information can be accessed at 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, the risks and costs associated with the integration of, and the ability of Globus Medical and NuVasive to integrate, their businesses successfully and to achieve anticipated synergies, 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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