



Bioventus Receives FDA 510(k) Clearance for SonaStar Elite

August 3, 2022

Innovative New Handpiece Addition to the Nexus Ultrasonic Generator

Significantly Expands Company's Offering in Neurosurgery Ablation Procedures

DURHAM, N.C., Aug. 03, 2022 (GLOBE NEWSWIRE) -- [Bioventus Inc.](#) (Nasdaq: BVS) ("Bioventus" or the "Company"), a global leader in innovations for active healing, announced the US Food and Drug Administration (FDA) has granted 510(k) clearance for the company's neXus® SonaStar Elite® handpiece. The SonaStar Elite (SSE) handpiece is powered by the neXus Ultrasonic Surgical Aspirator System, a next generation integrated ultrasonic surgical platform driven by a proprietary digital algorithm resulting in more versatility and control. The neXus system combines all the features of soft and hard (including bone) tissue removal into a single fully integrated platform capable of operating at multiple frequencies, including the newly approved 36 kHz SonaStar Elite Handpiece.

While the neXus system can be used in many clinical applications including neurosurgery, the SonaStar Elite handpiece has been cleared for resection of tumors with varying consistencies ranging from soft to firm, including the removal of malignant and benign brain and spinal tumors.

"The SonaStar Elite handpiece is the latest innovation in our neXus ultrasonic surgical pipeline," commented Andrew Hosmer, general manager, Surgical Solutions, at Bioventus. "Bioventus has a proven history of developing differentiated and market-leading technologies, and we remain committed to pursuing safe and effective best-in-class products that meet the needs of our surgeons and improve outcomes for their patients."

About Bioventus

Bioventus delivers clinically proven, cost-effective products that help people heal quickly and safely. Its mission is to make a difference by helping patients resume and enjoy active lives. The Innovations for Active Healing from Bioventus include offerings for pain treatment, restorative therapies and surgical solutions. Built on a commitment to high quality standards, evidence-based medicine and strong ethical behavior, Bioventus is a trusted partner for physicians worldwide. For more information, visit www.bioventus.com, and follow the Company on LinkedIn and Twitter. Bioventus and the Bioventus logo are registered trademarks of Bioventus LLC. BoneScalpel Access is a trademark and SonicOne, SonaStar and neXus are registered trademarks of Misonix, Inc.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of federal securities laws. Any statements contained herein that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements concerning the Company's future growth, operating margins, market leadership and strategy. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results to differ materially from those contemplated herein include, but are not limited to, the adverse impacts on our business as a result of the COVID-19 pandemic; our dependence on a limited number of products; our ability to develop, acquire and commercialize new products, line extensions or expanded indications; the continued and future acceptance of our existing portfolio of products and any new products, line extensions or expanded indications by physicians, patients, third-party payers and others in the medical community; our ability to achieve and maintain adequate levels of coverage and/or reimbursement for our products, the procedures using our products, or any future products we may seek to commercialize; our ability to recognize the benefits of our investments; our ability to complete acquisitions or successfully integrate new businesses, products or technologies in a cost-effective and non-disruptive manner; competition against other companies; our ability to continue to research, develop and manufacture our products if our facilities are damaged or become inoperable; failure to comply with the extensive government regulations related to our products and operations; enforcement actions if we engage in improper claims submission practices or in improper marketing or promotion of our products; the FDA regulatory process and our ability to obtain and maintain required regulatory clearances and approvals; the clinical studies of any of our future products that do not produce results necessary to support regulatory clearance or approval in the United States or elsewhere; and the other risks identified in the Risk Factors section of the Company's public filings with the Securities and Exchange Commission ("SEC"), including the Company's Annual Report on Form 10-K for the year ended December 31, 2021, as updated by the Company's Quarterly Report on Form 10-Q for the quarter ended April 2, 2022, and as such factors may be further updated from time to time in the Company's other filings with the SEC, which are accessible on the SEC's website at www.sec.gov. Except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement. Actual results may differ materially from those set forth in the forward-looking statements.

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