



## SeaSpine Announces FDA 510(k) Clearance of 7D Surgical Percutaneous Spine Module for Minimally Invasive Surgery

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CARLSBAD, Calif., July 07, 2021 (GLOBE NEWSWIRE) -- SeaSpine Holdings Corporation (NASDAQ: SPNE), a global medical technology company focused on surgical solutions for the treatment of spinal disorders, today announced the FDA 510(k) clearance of its 7D Percutaneous Spine Module for minimally invasive surgery. This represents a new application and increased functionality for its 7D Flash™ Navigation System. This news follows SeaSpine's recent acquisition of 7D Surgical, a Toronto-based company that develops advanced optical technologies and machine vision-based registration algorithms for surgical navigation to improve patient care. The Company is preparing a limited release of the Percutaneous Spine Module in the third quarter.

"We are extremely excited to achieve FDA clearance and eager to deploy our Percutaneous Spine Module," said Beau Standish, President of Enabling Technologies at SeaSpine. "This new application will help address an important part of the spine navigation market and will nicely round out our FLASH Navigation Spine portfolio. We anticipate this MIS application to be a valuable enhancement for both ambulatory surgery centers and hospitals. I'm very proud of what our team has accomplished thus far, but this is still just the beginning of where we will take our machine vision technology in the future."

The 7D FLASH Navigation System uses visible light to create a three-dimensional image for surgical navigation in just seconds, which is expected to result in shorter and more efficient spinal procedures. It is the only regulatory-cleared image guidance system that utilizes this novel and proprietary camera-based technology, coupled with machine-vision algorithms, to eliminate the long-standing frustrations with legacy surgical navigation platforms. The speed, accuracy, and efficiency of machine-vision technology is intended to provide significant economic value and harnesses the true potential of image guided navigation surgery.

"We are very happy with the integration of 7D Surgical into the SeaSpine family," stated Keith C. Valentine, President and Chief Executive Officer at SeaSpine. "This is the first new product introduction as a combined team and continues to demonstrate our innovative philosophy and approach to improve spine surgery and deliver clinical value to the surgeon, staff, and patient. We believe that participation in the full continuum of care for each patient will deliver clinical value and accelerate our market-share taking strategy."

The 7D FLASH Navigation System is designed to improve workflows in surgical procedures. The Spine Module has FDA 510(k) clearance, Health Canada MDL approval, and CE Mark for spinal navigation. The Percutaneous Spine Module has FDA 510(k) clearance for spinal navigation. The Cranial Module has FDA 510(k) clearance and Health Canada MDL approval for cranial navigation.

### About SeaSpine

SeaSpine ([www.seaspine.com](http://www.seaspine.com)) is a global medical technology company focused on the design, development and commercialization of surgical solutions for the treatment of patients suffering from spinal disorders. SeaSpine has a comprehensive portfolio of orthobiologics and spinal implants solutions, as well as a market leading surgical navigation system, to meet the varying combinations of products and enabling technologies that neurosurgeons and orthopedic spine surgeons need to perform fusion procedures on the lumbar, thoracic and cervical spine. SeaSpine's orthobiologics products consist of a broad range of advanced and traditional bone graft substitutes that are designed to improve bone fusion rates following a wide range of orthopedic surgeries, including spine, hip, and extremities procedures. SeaSpine's spinal implants portfolio consists of an extensive line of products to facilitate spinal fusion in degenerative, minimally invasive surgery (MIS), and complex spinal deformity procedures. Expertise in orthobiologic sciences, as well as spinal implants and software product development, allows SeaSpine to offer its surgeon customers a differentiated portfolio and a complete solution to meet their fusion requirements. SeaSpine currently markets its products in the United States and in approximately 30 countries worldwide through a committed network of increasingly exclusive distribution partners.

### Forward-Looking Statements

SeaSpine cautions you that statements included in this news release that are not a description of historical facts are forward-looking statements that are based on the Company's current expectations and assumptions. Such forward-looking statements include, but are not limited to, statements relating to: the timing of the limited release of the Percutaneous Spine Module; whether the MIS application will be a valuable enhancement for both ambulatory surgical centers and hospitals; SeaSpine's ability to advance machine-vision technology in the future, including expanding the application of 7D FLASH Navigation System technology to other surgical specialties and the ability for SeaSpine to accelerate the development of additional software and systems; the ability of the 7D FLASH Navigation System to result in shorter and more efficient spinal procedures, eliminate long-standing frustrations with legacy surgical navigation platforms, and provide significant economic value, as well as harnesses the true potential of image guided navigation surgery; the timing and success of the integration of 7D Surgical; the ability of participating in the full continuum of care to deliver clinical value and accelerate SeaSpine's market-share taking strategy; and the potential for the 7D FLASH Navigation System to improve workflows in surgical procedures. Among the factors that could cause or contribute to material differences between the SeaSpine's actual results and the expectations indicated by the forward-looking statements are risks and uncertainties that include, but are not limited to: the ability of newly launched products to perform as designed and intended and to meet the needs of surgeons and patients, including as a result of the lack of clinical validation of products in limited commercial (or "alpha") launch; risks inherent in recent acquisitions, such as with 7D Surgical, or the use of nascent imaging techniques, including advanced optical technologies and machine vision-based registration algorithms; challenges and/or delay in reaching agreement with hospital customers with respect to the placement of capital equipment and the terms of any hospital purchase commitments, including the inability to place the 7D Surgical System as result of prior placement of competitive systems or conflicting purchase commitments; unexpected delay, including as a result of developing and supporting the deployment of new products, the fact that newly launched products may require substantial additional development activities, which could introduce further expense and delay, or as a result of obtaining regulatory clearances; general economic and business conditions in the markets in which the Company does business, both in the U.S. and abroad; and other risks and uncertainties more fully

described in the Company's news releases and periodic filings with the Securities and Exchange Commission. The Company's public filings with the Securities and Exchange Commission are available at [www.sec.gov](http://www.sec.gov).

You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date when made. SeaSpine does not intend to revise or update any forward-looking statement set forth in this news release to reflect events or circumstances arising after the date hereof, except as may be required by law.

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