Alphatec Announces FDA Clearance of its Automated SafeOp Neuromonitoring System to Address Significant Unmet Needs in Spine Surgery

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CARLSBAD, Calif., Feb. 25, 2019 (GLOBE NEWSWIRE) -- Alphatec Holdings, Inc. ("ATEC" or the "Company") (Nasdaq: ATEC) announced today that it has received 510(k) clearance from the U.S. Food & Drug Administration (FDA) for its automated SafeOp neuromonitoring system for use in real-time intraoperative nerve location and health assessment.

"I could not be more excited to integrate this revolutionary technology into our growing number of spine approaches," said Pat Miles, Chairman and Chief Executive Officer. "Many of us at ATEC were previously instrumental in developing, validating, and marketing a neuromonitoring platform that became foundational to a billion-dollar spine company. The SafeOp solution is better. It has no peer and it elevates the requirements for others to participate. Today, we have raised the bar in delivering objective actionable information that drives safer and more reproducible spine surgery."

The next-generation technology of the SafeOp system represents a significant advancement in two intraoperative neurophysiological monitoring (IONM) modalities: somatosensory evoked potential (SSEP), and electromyography (EMG). SSEP assesses the functional health of the spinal cord and nerves, while EMG enables surgeons to test nerves for their location, proximity, and conduction. The SafeOp automated SSEP technology has been successfully used in more than 1,000 surgeries to identify potential nerve injury from patient positioning, and has demonstrated reliability in monitoring peripheral nerves in spine surgery. The current 510k clearance expands the system to include more advanced algorithms for EMG.

"Surgeons yearn for information to enable better surgery," added Miles. "SafeOp not only provides actionable intraoperative information regarding nerve location during access, but for the first time, it also allows surgeons to monitor patient nerve health, in real-time, during surgery. The development of this system demonstrates ATEC's commitment to revolutionize how the world approaches spine surgery."

The SafeOp system's initial focus will be on resolving the significant unmet clinical need in minimally invasive lateral procedures, but it can and will be leveraged into multiple ATEC surgical approaches.

"Neuromonitoring technology is critical for a safe and reproducible lateral surgery," said Luiz Pimenta, MD, PhD, ATEC's Chief Medical Officer and pioneer of the lateral surgery approach. "The SafeOp system has not only improved the EMG capability to find nerves, but now surgeons will be able to monitor the health of nerves in the lumbar plexus throughout the entire procedure. This technology will provide more surgeons with the confidence to perform lateral surgeries and will improve patient care."

ATEC expects full commercial launch of the SafeOp system in Spring 2019. It is the first solution delivered as part of the Alpha Informatix™ platform, which ATEC plans to expand to provide surgeons with intraoperative information beyond neuromonitoring.

About the SafeOp Neuromonitoring System

The foundational technology of ATEC's SafeOp system was obtained as part of the acquisition of SafeOp Surgical, Inc. in March 2018 and has been further developed over the past year.

Key features of the SafeOp system include:

- A technologically advanced solution that combines real-time, automated EMG and SSEP to enable objective assessment of nerve location and nerve health throughout the entire surgical procedure
- An EMG algorithm that provides high-speed, validated response feedback unlike other solutions on the market that are more susceptible to electrical noise in the operating room
- A SSEP processing that incorporates unique "signal-to-noise ratio" technology and rapid processing, allowing SafeOp to reproducibly monitor small nerves every 3 seconds, while other systems on the market have up to 5 minutes of latency
- A solution that is uniquely equipped to address the L4/L5 spinal level in minimally invasive lateral surgical procedures, the level most difficult to safely access but most commonly treated
- Technology that is designed to integrate into ATEC's broader suite of solutions for unprecedented predictability and improved spine outcomes

"Having spent much of my career developing successful intraoperative neuromonitoring systems and working with spine surgeons to understand their requirements in the operating room, I can say that the SafeOp system is by far the most advanced system on the market. I have been very impressed with the system's technical and user experience performance. We have leaped ahead of other available technologies," said Jim Gharib, ATEC's Senior Director, Adjunctive Technologies.

About Alphatec Holdings, Inc.

Alphatec Holdings, Inc., through its wholly-owned subsidiaries, Alphatec Spine, Inc. and SafeOp Surgical, Inc., is a medical device company that

designs, develops and markets spinal fusion technology products and solutions for the treatment of spinal disorders associated with disease and degeneration, congenital deformities and trauma. The Company markets its products in the U.S. via independent sales agents and a direct sales force.

Additional information can be found at www.atecspine.com.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainty. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The Company cautions investors that there can be no assurance that actual results will not differ materially from those projected or suggested in such forward-looking statements as a result of various factors. Forward-looking statements include references to the Company's planned commercial launches, product introductions and product integration, surgeon and market acceptance of Company products, solutions and platforms, and the Company's ability to deliver key product features. The important factors that could cause actual operating results to differ significantly from those expressed or implied by such forward-looking statements include, but are not limited to: the uncertainty of success in developing new products or products currently in the Company's pipeline; failure to achieve acceptance of the Company's products by the surgeon community; failure to obtain FDA or other regulatory clearance or approval for new products, or unexpected or prolonged delays in the process; continuation of favorable third party reimbursement for procedures performed using the Company's products; the Company's ability to compete with other products and with emerging new technologies; product liability exposure; patent infringement claims; and claims related to the Company's intellectual property. The words "believe," "will," "should," "expect," "intend," "estimate," "look forward" and "anticipate," variations of such words and similar expressions identify forward-looking statements, but their absence does not mean that a statement is not a forward-looking statement. A further list and description of these and other factors, risks and uncertainties can be found in the Company's most recent annual report, and any subsequent quarterly and current reports, filed with the Securities and Exchange Commission. ATEC disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, unless required by law.

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