Press release

SpineGuard® receives US FDA clearance to market PediGuard® Threaded DSG™ device

PARIS and SAN FRANCISCO, June 16, 2016 – SpineGuard (FR0011464452 – ALSGD), an innovative company that develops and markets disposable medical devices that empower surgeons to enhance clinical outcomes and simplify surgeries, announced today it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its new PediGuard Threaded DSG™ device.

"We are very excited by the clearance of our PediGuard Threaded device, which brings a new generation of DSG™-enabled probes to the US market, offering spine surgeons the added clinical benefit of reducing surgical steps in fusion surgery. This clearance allows our network of agents to initiate the commercial phase of this unique value proposition in a $7-billion market that is under price pressure and in tremendous need for differentiation," said Stéphane Bette, Co-founder, CTO and US General Manager of SpineGuard**.**

Pierre Jérôme, Co-founder and CEO of SpineGuard, concluded: *"We have received very positive feedback on our new DSG™ device from our spine surgeon customers in Europe and Asia since its introduction earlier this year. We were eager to extend its benefits to surgeons, patients and hospitals in the US. In line with healthcare systems' expectations of better clinical outcomes and surgical efficiency, SpineGuard continues to bring real-time digital technology to the operating room."*

The PediGuard Threaded device with DSG technology embedded inside may be used in open or minimally invasive approaches for pedicle screw insertion. It is available in various designs to accommodate surgeons' preferences and patients' anatomy. A single-use DSG pin embedded with the bipolar sensor is inserted into the cannula of the threaded shaft and connected to the electronic processor inside the single-use DSG handle. The distal tip of the threaded shaft includes an awl-like tip to facilitate redirection of the device until the tip is past the pedicle isthmus.

More information on the DSG™ technology, its new applications and surgeons' testimonials **here**.

Latest news release: PediGuard Threaded devices launched at SpineWeek (May 10, 2016).

Next financial press release: 2016 Half-year revenue on July 12, 2016.

About SpineGuard®

Co-founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard's mission is to make spine surgery safer by bringing real-time digital technology into the operating room. Its primary objective is to establish its proprietary DSG™ (Dynamic Surgical Guidance) technology as the global standard of surgical care, starting with safer screw placement in spine surgery and then in other surgeries. PediGuard®, the first device designed using DSG, was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. It is the world's first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Over 45,000 surgical procedures have been performed worldwide with PediGuard. Numerous studies published in peer-reviewed medical and scientific journals have demonstrated the multiple benefits that PediGuard delivers to patients, surgical staff and hospitals. In 2015, SpineGuard started to expand the applications of DSG into pedicle screws through partnerships with innovative surgical companies in France and the US. SpineGuard has offices in San Francisco and Paris.

For further information, visit www.spineguard.com.

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