

SpineGuard reaches a significant regulatory milestone to strengthen its PediGuard® offering in China

Submission of a file to the Chinese authorities (NMPA) to obtain renewed approval for the currently available range of PediGuard in China, as well as its extension to add the Curved and XS PediGuard models

PARIS and BOULDER (CO), March 5, 2024 at 06:00 pm CET – **SpineGuard** (FR0011464452 – ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) unique sensing technology using electrical conductivity local measurement in real time to secure and streamline the placement of bone implants, today announces a key progress in its Chinese regulatory plan with the submission to the Chinese authorities (NMPA) of a file seeking clearance renewal for the currently available range of PediGuard in China, as well as its extension to add the Curved and XS PediGuard models for which the necessary tests for regulatory purposes have been launched in a specialized Chinese laboratory.

Stéphane Bette, Deputy CEO and Co-Founder of SpineGuard, declares: *“This key milestone is a great satisfaction for the teams of SpineGuard and XinRong Medical Group, our commercial partner in China. We execute on our roadmap with the following double objective for the 2024 third quarter: the renewal of the authorization for the current range, and the clearance of PediGuard models which are not yet available in China, while they are in other geographies such as Europe or the United States where they have encountered true commercial success. Indeed, the curved tip features an asymmetrical sensor that provides the surgeon with a directional information, allowing to detect a cortical bony wall and to redirect away from it in order to avoid the breach. To use a simple analogy, the curved device can be used as a seeker head in bone. This is particularly useful in scoliosis treatment where the vertebral anatomy can be complex and deformed. The “XS” models benefit a miniaturized sensor allowing for utilization in pediatric surgery or in the cervical spine, where the anatomy is tiny. XinRong will thereby soon possess the proper range of products instrumental to PediGuard commercial success in China. We will not stop there, since this regulatory filing will be followed by those of Cannulated and Threaded PediGuard, specifically useful in posterior minimally invasive and anterior approaches of the Spine.”*

Perspectives

As a reminder, in order to get back to double digit growth from 2024 onwards, SpineGuard is intensifying its commercial efforts, in particular in the United States, and will be introducing three new products derived from its DSG technology:

1. PediGuard Threaded adapted to scoliosis correction via anterior approach;
2. Cannulated PediGuard for sacroiliac fusion in collaboration with Omnia Medical; and
3. DSG Drill Bit compatible with power drills and navigation.

In parallel, the Company is actively working on obtaining the clearance of the whole PediGuard product range in China and seeking partners for dental implantology and surgical robotics.

About SpineGuard®

Founded in 2009 in France and the USA by Pierre Jérôme and Stéphane Bette, SpineGuard is an innovative company deploying its proprietary radiation-free real time sensing technology DSG® (Dynamic Surgical Guidance) to secure and streamline the

placement of implants in the skeleton. SpineGuard designs, develops and markets medical devices embedding its technology. Over 100,000 surgical procedures have been secured worldwide thanks to DSG® and 32 studies published in peer-reviewed scientific journals have demonstrated the multiple benefits DSG® offers to patients, surgeons, surgical staff and hospitals. Building on these strong fundamentals and several strategic partnerships, SpineGuard is expanding the scope of its DSG® technology to the treatment of scoliosis via anterior approach, sacroiliac joint fusion, dental implantology and innovations such as the « smart » pedicle screw and power drill or surgical robotics. DSG® was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer. SpineGuard has engaged in multiple ESG initiatives.

For further information, visit www.spineguard.com

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