

## SpineGuard files its “510K” dossier in the US for the clearance of its new smart drilling device dedicated to sacroiliac joint fusion

- *Innovation developed in partnership with the US company Omnia Medical*
- *Acceleration of commercial deployment of SpineGuard in the United States*

**PARIS and BOULDER (CO), July 17, 2024 – 6:00 pm CEST – SpineGuard** (FR0011464452 – ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) local conductivity sensing technology to secure and streamline the placement of bone implants, today announces the filing of its “510K” regulatory dossier in the US with the FDA, seeking clearance to commercialize its new device designed to secure the Posterior sacroiliac Fusion (PsiF) surgical procedure.

**Stéphane Bette, Deputy CEO and Co-Founder of SpineGuard, stated:** *“We are very pleased by the collaboration with Omnia Medical, which allowed us to develop a new product embedded with our DSG sensor to assist with the correct positioning of implants during sacroiliac joint fusion procedures. It is a PediGuard variant in the shape of a needle, named “PsiFGuard”, that enables the surgeon to ensure that the implant is positioned precisely in the joint. Our DSG technology is indeed capable of differentiating the joint from the surrounding bony structures: the sacrum and the ilium. PsiFGuard is an instrument that also features connectivity to the DSG Connect App, for visualization and recording of the data. This project illustrates well our deployment strategy for our technology in new growth-generating applications, through partnerships with industry players in our sector. Many patients are suffering from a degenerative sacroiliac joint, which causes debilitating pain. Its treatment via posterior fusion surgery is a procedure developing rapidly due to its technical simplicity and low associated risk. However, there are here two key challenges: the correct placement of the implant in the joint that is very difficult to localize via X-Ray imaging and the strong primary stability of the implant. SpineGuard answers the first one by offering DSG guidance, while Omnia Medical answers the second with an innovative implant design. In collaborating to associate our technologies in one combined product offering, we will then soon answer the unmet clinical need perfectly.”*

**Troy Schifano, CEO and Co-Founder of Omnia Medical, added:** *“As early pioneers in posterior sacroiliac joint fusion, Omnia has witnessed firsthand how important consistently locating the joint is to the success of the procedure. This seemingly straight-forward step is the key to placing the implant accurately, giving it the correct environment to facilitate fusion. The PsiFGuard will give physicians the immediate feedback needed to properly place the initial PsiF instrumentation and, ultimately, the implant. The security provided by PsiFGuard will allow both physicians and patients to feel confident that PsiF was the right choice for treating their chronic sacroiliac pain. Together with SpineGuard, Omnia looks forward to bringing this long overdue technology to the sacroiliac joint fusion market, as we continue being the innovation leader in posterior sacroiliac joint repair.”*



PsiFGuard with wireless transmission

Software for tablet

### The sacroiliac fusion market

More than 15% of patients suffering from back pain are estimated to have a degenerative sacroiliac joint causing debilitating pain. The global market of sacroiliac joint fusion reached more than 539 million dollars in 2021, projected to grow at a 19% CAGR (compound annual growth rate) from 2022 to 2030 according to Grandview Research. A new payment code implemented in the United States in January 2024 for posterior sacroiliac joint fusion surgery should accelerate this progression.

### SpineGuard's Priorities

SpineGuard intends to continue its sales drive, particularly in the United States, and market rollout of three new products embedding DSG® technology and satisfying unmet clinical needs (the PediGuard Threaded adapted to scoliosis correction via anterior approach, the PediGuard Canulated designed for sacroiliac fusion named PsiFGuard, and the DSG Universal Drill Bit compatible with power drills and surgical navigation in the spine) in order to sustain double-digit growth in the coming quarters. The Company is also working on clearing the entire PediGuard range in China, as well as establishing strategic partnerships in the dental implantology and surgical robotic fields.

### 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 34 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](http://www.spineguard.com)

### About Omnia Medical

Top medical device engineers and industry professionals came together in 2014 to form Omnia Medical, an orthopedic implant company located in Morgantown, WV. Omnia Medical's mission is to develop novel products that reduce operative time through safe and reproducible instrumentation, while achieving superior surgical outcomes. Ongoing surgeon collaboration helps the company achieve this mission, which leads to critical cost savings for healthcare providers and their patients. Omnia Medical has created a comprehensive range of spine implants, including a proprietary line of interbodies with TiBrid osseointegrative surface technology, and is notable for being among the pioneers in posterior sacroiliac joint (SIJ) fusion. For more information, visit [www.OmniaMedical.com](http://www.OmniaMedical.com).

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