

## SpineGuard obtains FDA clearance for commercial release of its “PsiFGuard” new smart drilling device dedicated to sacroiliac joint fusion

- Innovation developed in partnership with the US company Omnia Medical
- Key milestone for the deployment of the DSG® technology in the United States

**PARIS (France) and BOULDER (CO, USA), September 30, 2024** – 7:00 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, announced today the authorization under 510K #241895 by the FDA (Food and Drug Administration) to commercialize in the United States its new PsiFGuard 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 this new clearance that will help us accelerate our growth as we continue to deliver consistently on our new product road map. The efficacy of our PsiFGuard device in locating the SI joint was clearly demonstrated in the submitted pre-clinical testing which allowed for a smooth clearance process. With this new sacroiliac application, after the previously cleared anterior approach to the spine, we keep broadening the scope of our DSG technology. We are particularly excited to collaborate with Omnia Medical to bring to the market such innovative solution combining our technologies to address unmet clinical needs.”*

**Troy Schifano, CEO and Co-Founder of Omnia Medical, added:** *“We’ve seen that proper placement of the implant is essential to a successful SI Joint fusion. Locating the joint is critical for this to occur but can be very challenging. However, the data SpineGuard provided to the FDA during the clearance process has confirmed PsiFGuard drastically enhances the accuracy of the placement of the wire guiding the implant. We are thrilled about bringing this technology to market as it will give physicians and patients comfort knowing that they will have the highest chance of SI joint fusion success. Like Omnia, SpineGuard continues to be a leader and innovator in their respective field, and we could not be more excited about our partnership with them.”*



## 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.

## H2 2024 outlook

In the second half of 2024, SpineGuard is focused on accelerating its sales growth, particularly in the United States, rolling-out PsiFGuard as well other new products, and registering its full line in China. The Company is also working on building strategic partnerships and strengthening its financial position.

### 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).

### Disclaimer

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