

SpineGuard obtains FDA clearance for commercial release of its new “DSG Connect” platform in the USA

PARIS and BOULDER (CO), February 15, 2021 – 11:30 CET - SpineGuard (FR0011464452 – ALSGD), an innovative company that deploys its DSG® (Dynamic Surgical Guidance) sensing technology to secure and streamline the placement of bone implants, announced today the clearance under 510K #201454 by the FDA (Food and Drug Administration) for commercial release of its DSG Connect platform in the United States.

The FDA clearance allows for commercial launch in the USA of a new generation of PediGuard probes and smart screws for spine surgery, capable of transmitting their X-Ray free, real time information thanks to the DSG Connect module. A wireless tablet interface embedded with a dedicated software application receives the signal sent by the DSG sensor and adds visual rendering to the audio feedback in order to optimize its exploitation in the operating room. It also allows for data recording for the purpose of medical legal evidence as well as the performance of clinical studies on the topic of bone quality. Ultimately, the commercial status in the United States of this platform already used experimentally to guide orthopedic surgical robots facilitates its potential integration within robotic and navigation systems in the market place.

Stéphane Bette, cofounder and deputy CEO of SpineGuard, declares: " *This FDA clearance opens the doors of the American market to our X-Ray free real time surgical guidance, from now on connected and more powerful thanks to new functionalities. It also affirms SpineGuard's position as a significant player in digital surgery. DSG has the potential to be deployed throughout the entire orthopedic and dental fields, and in particular in robotic applications.*"



Modified electronic board with wireless transmitter



Software application on tablet

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 that have been used in over 80,000 surgical procedures worldwide. Sixteen studies published in peer-reviewed scientific journals have demonstrated the multiple benefits DSG® offers to patients, surgeons, surgical staff and hospitals. Building on these solid fundamentals and several strategic partnerships, SpineGuard has expanded its technology platform in a disruptive innovation: the « smart » pedicle screw launched late 2017 and is broadening the scope of applications in dental implantology and surgical robotics. DSG® was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer.

For further information, visit www.spineguard.com

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