

SpineGuard files its “510K” dossier for the clearance of its new “DSG Connect” platform in the United States

PARIS and BOULDER (CO), June 4, 2020 – 06:00pm CEST - **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 filing of its “510K” regulatory dossier with the FDA, seeking the authorization to commercialize its DSG Connect platform in the USA.

Already being utilized experimentally in a new strategic high value platform to guide surgical robots, SpineGuard will now apply this platform to its entire range of products. The commercialization in the United States will commence as soon as the file is validated, which usually takes 3 to 9 months. As a reminder, DSG Connect is a tablet based software interface that adds visual interpretation to the auditory feedback for optimal exploitation of the signal during pedicle screw placement. It also allows for data recording of bone impedance values as evidence of optimal screw placement within the pedicle and for bone quality studies.

Stéphane Bette, co-founder and Deputy CEO of SpineGuard, said: *“SpineGuard generates a large portion of its revenue in the United States, the first market worldwide in our sector that strongly rewards innovation. Therefore, it is our priority to quickly clear there the innovations that we launch. We are very proud, during the COVID period, to have assembled this regulatory file which is substantial because for the first time in the history of the company it entails radio frequency transmission, as well as a software application on a visual terminal. On the heels of the recent CE mark, as spine surgeries progressively resume in Europe, we will soon perform the first surgery in France with DSG Connect, and we look forward to doing the same in the USA. DSG Connect is a major step in the development of the company and the deployment of the DSG technology, not only because of the commercial potential but also due to the strategic value of this new platform. DSG Connect is also an essential component of the application for surgical robots aiming at enhancing their safety and autonomy. We are progressing this application rapidly for which we are in discussions with potential strategic partners.”*



Modified electronic board with wireless transmission



DSG connect
Software for 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 75,000 surgical procedures worldwide. Fifteen 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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