

SpineGuard obtains FDA clearance for commercial release of its “Threaded PediGuard” in anterior approach spine surgery

PARIS and BOULDER (CO), April 4, 2022, at 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 authorization under 510K #220160 by the FDA (Food and Drug Administration) to commercialize in the United States its Threaded PediGuard device for anterior approach instrumented spine surgery.

Stéphane Bette, co-founder and Deputy CEO of SpineGuard, said: *“SpineGuard’s revenues are largely generated by the US market which is also the first market worldwide in our sector that strongly rewards innovation. Therefore, our priority is to quickly clear the innovative applications that we launch. We are very pleased to have obtained this important regulatory clearance in record times since we just filed last January this year. It is the very first file in the company’s history to demonstrate the efficacy of our PediGuard device in a new spinal application different from pedicle screw trajectory preparation: accurately facilitating the insertion of screws in vertebral bodies from an anterior approach. We will now be able to fulfill the strong demand from our users to use the Threaded PediGuard and its DSG Connect interface in anterior approach, particularly for deformity correction, as it has evolved into an increasingly growing market. This clearance integrates perfectly in the context of the already promising strategic collaboration with Wishbone Medical, in order to boost our mutual sales in the adolescent surgery segment.”*



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 85,000 surgical procedures worldwide. Nineteen 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 has expanded the scope of its DSG® technology in innovative applications such as the « smart » pedicle screw, the DSG Connect visualization and registration interface, 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. SpineGuard has engaged in multiple ESG initiatives.

For further information, visit www.spineguard.com

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