

SpineGuard files its “510K” dossier for the clearance of its “Threaded PediGuard” in anterior approach spine surgery

PARIS and BOULDER (CO), January 31, 2022 at 06:00 pm– **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 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 broach and clear the regulatory pathway tied to the innovative applications that we launch. We are very pleased to have assembled this regulatory file which is substantial because for the first time in the history of the company it supports 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. The Threaded PediGuard and its DSG Connect interface presents the most elaborate device of our range today. This paired solution triggered the highest demand from our users to address the anterior application, particularly for deformity correction, as it has evolved into an increasingly growing market. This envisioned clearance integrates perfectly in the context of the recently announced strategic collaboration with Wishbone Medical, in order to boost our mutual sales in the adolescent surgery segment.”*



Threaded PediGuard 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 85,000 surgical procedures worldwide. Eighteen 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. SpineGuard has engaged in multiple ESG initiatives.

For further information, visit www.spineguard.com

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Contacts

SpineGuard

Pierre Jérôme

CEO & Chairman

Tel: +33 1 45 18 45 19

p.jerome@spineguard.com

SpineGuard

Manuel Lanfossi

CFO

Tel: +33 1 45 18 45 19

m.lanfossi@spineguard.com

NewCap

Investor Relations & Financial Communication

Mathilde Bohin / Pierre Laurent

Tel.: +33 1 44 71 94 94

spineguard@newcap.eu

