Press release

SpineGuard successfully passes ANVISA's inspection, paving the way for registration of its new products in Brazil

PARIS and SAN FRANCISCO, Dec. 1st, 2014 – **SpineGuard** (FR0011464452 – ALSGD) announced today that it has received certification from the Brazilian governmental regulatory authority ANVISA (Agência Nacional de Vigilância Sanitária) following a three-day inspection in Paris. Such certification by ANVISA has recently become the mandatory precursor to register new medical devices for marketing in Brazil.

"*This ANVISA certification consolidates our regulatory position in Brazil, an important market for SpineGuard,*" said **Pierre Jérôme**, Co-founder and Chief Executive Officer of SpineGuard. *"It will allow us to initiate the registration process for the Curved, Cannulated and XS versions of PediGuard in this large market."*

Recently, SpineGuard's Dynamic Surgical Guidance technology was recognized by Becker's Healthcare, a leading spine industry authority, with the "2014 Spine Device Award" for "advancing spine technology and patient care and representing both the cutting-edge and gold standard in spine care."

About SpineGuard®

Co-founded in 2009 by Pierre Jérôme and Stéphane Bette, former executives at Medtronic Sofamor-Danek and SpineVision, SpineGuard's primary objective is to establish its FDA-cleared and CE-marked PediGuard® device as the global standard of care for safer screw placement in spine surgery. SpineGuard's mission is to make spine surgery safer. The company is also exploring other applications for its Dynamic Surgical Guidance technology platform. SpineGuard has offices in San Francisco and Paris. For further information, visit www.spineguard.com.

About PediGuard®

Co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger, M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer, PediGuard is the world's first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Real-time feedback is provided via audio and visual signals. Close to 35,000 procedures have been performed with PediGuard worldwide. Several studies published in peer-reviewed medical and scientific journals have demonstrated that PediGuard detects 98% of pedicle breaches, presents an average screw placement accuracy of 97% (vs. 92% for surgical navigation), provides 3-fold less pedicle perforations than with free-hand technique and a 3-fold reduction in neuro-monitoring alarms. It also limits radiation exposure by 25-30% and decreases by 15% the time for pedicle screw placement.

About pedicle screw-based stabilization

Pedicle screw-based stabilization has become the gold standard for treating spine instabilities and deformities. This market is growing due to the increasing number of patients requiring surgical treatment and a larger number of surgeons being trained in pedicle screw-based technologies. Technological advancements such as minimally invasive surgery, bone substitutes, dynamic stabilization and thoracic screws further reiterate the importance of pedicle screw placement. However, accuracy of pedicle screw placement remains a critical issue in spine surgery. In recently published papers studying screw placement accuracy, the average rate of misplaced screws is approximately 20% (Verma 2010, Tian 2011, Gelalis 2011, Mason 2013) with 2-11% of patients presenting neurologic complications (Amiot 2000, Amato 2010, Waschke 2012, Oh 2013, Koktekir 2014, Nevzati 2014) and 2-6% of patients having risk of vascular complications (Sarlak 2009, Sarwahi 2014, Parker 2014) due to misplaced screws.

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