DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 12, 2017

SpineGuard, S.A.
% John Smith, MD, JD
Partner
Hogan Lovells U.S. LLP
555 Thirteenth Street NW
Washington, DC 20004

Re: K162884
Trade/Device Name: SpineGuard DSG Zavation Screw System
Regulation Number: 21 CFR 882.4300
Regulation Name: Manual Cranial Drills, Burrs, Trephines, and Their Accessories
Regulatory Class: Class II
Product Code: HBG
Dated: October 14, 2016
Received: October 14, 2016

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162884

Device Name
SpineGuard DSG Zavation Screw System

Indications for Use *(Describe)*
The DSG™ Zavation Screw System is indicated for use with Zavation pedicle screws during pedicle screw insertion to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the pedicle screw and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The DSG™ Zavation Screw System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine, with options of direct insertion of the screw in bone or after a step of preparation of the pilot hole with sensor equipped instruments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

SpineGuard, S.A.'s DSG™ Zavation Screw System

Sponsor

SpineGuard, S.A.

10 cours Louis Lumière

Vincennes, France 94300

Phone: +33 1 45 18 45 19
Facsimile: +33 1 45 18 45 20

Contact Person: Stephane Bette

Date Prepared: December 19, 2016

Name of Device: DSG™ Zavation Screw System

Common or Usual Name: Manual cranial drill and accessories

Classification Name: 21 C.F.R. § 882.4300 (Manual cranial drills, burrs, trephines, and their accessories)

Classification Panel: Neurology

Regulatory Class: Class II

Product Code: HBG

Predicate and Reference Devices

SpineGuard, S.A. DSG™ Threaded Drill System (K152747, Predicate)

Zavation Spinal System (K153404, Reference)

Device Description

The DSG™ Zavation Screw System is a modification to the cleared DSG™ Threaded Drill System and consists of the DSG™ Electronic T-handle, Ratcheting Handle, DSG™ Pin (active stylet), and the previously cleared Zavation Spinal System (K153404). These components are purchased and shipped as a complete system from Zavation, with the DSG™ Threaded Drill System components and Zavation Spinal System components individually packaged. The complete system is provided with the modified instructions for use of the DSG™ Zavation Screw System.

All of the patient-contacting materials are categorized per FDA's guidance on ISO 10993-1 as externally communicating materials that are in contact with the body for a limited duration, and are unchanged from the prior clearance. Certain components of the device are single-use while

others are re-usable; certain components are provided sterile while others are sterilized by the end user.

The device is intended for use by surgeons in a professional healthcare environment, and utilizes sensing technology to detect the impedance of immediately surrounding tissues while inserting pedicle screws either through a previously drilled pilot hole or directly into bone. The surgeon can either drill and/or tap the screw hole prior to inserting the pedicle screw, or can use the system to directly insert the screw into the bone without a pilot hole. As the screw is manually advanced into the bone, the distal sensor measures the electrical impedance of the immediately surrounding tissues. The device produces real-time visual and audible signals to indicate changes in impedance associated with possible vertebral perforation.

Intended Use / Indications for Use

The DSG™ Zavation Screw System is indicated for use with the Zavation Spinal System during pedicle screw insertion to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the pedicle screw and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The DSG™ Zavation Screw System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine, with options of direct insertion of the screw in bone or after a step of preparation of the pilot hole with sensor equipped instruments.

Summary of Technological Characteristics

The subject and predicate devices function based on the same technological principles, including the sensing of tissue impedance in tissues surrounding the targeted treatment area. At a high level, both devices are based on the following same technological elements:

- Both devices contain the DSG™ Electronic T-handle, Ratcheting Handle, and DSG™ Pin (active stylet). These components are unmodified from the predicate clearance (K152747).

The following technological differences exist between the subject and predicate devices:

- The subject device does not include the DSG™ Threaded Drill shaft or DSG™ Sleeve components, in order to facilitate use with the cleared Zavation Spinal System.

A table comparing the key features of the subject and predicate devices is provided below.

	DSG™ Zavation Screw System (*subject device*)	**DSG™ Threaded Drill System (K152747)**
Intended Use / Indications for Use	The DSG™ Zavation Screw System is indicated for use with the Zavation Spinal System during pedicle screw insertion to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the pedicle screw and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The DSG™ Zavation Screw System is indicated	The DSG™ Threaded Drill System is intended to be used for the preparation of pedicle screw holes. The DSG™ Threaded Drill System is indicated for use during pedicle screw pilot hole drilling to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The DSG™

	DSG™ Zavation Screw System (*subject device*)	DSG™ Threaded Drill System (K152747)
	for use in both open and percutaneous (MIS) surgical approaches to the spine, with options of direct insertion of the screw in bone or after a step of preparation of the pilot hole with sensor equipped instruments.	Threaded Drill System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. The DSG™ Threaded Drill System is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine. The DSG™ Threaded Drill System also is specifically indicated for use in intraoperative electromyographic ("EMG") surveillance to assist in the location and evaluation of spinal nerves during surgery of the spine, by administration of low voltage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves.
Handle Shape	T-Handle with Ratchet	T-Handle with Ratchet
Components	DSG™ Electronic T-handle, Ratcheting Handle, and DSG™ Pin (active stylet)	DSG™ Electronic T-handle, Ratcheting Handle, and DSG™ Pin (active stylet), DSG™ Threaded Drill shaft and DSG™ Sleeve
Safety Features	Device cannot be turned off until battery exhausted. Prevents reuse of device.	Device cannot be turned off until battery exhausted. Prevents reuse of device.
Power Source	Lithium-Ion Battery	Lithium-Ion Battery
Sterility	Sterile/Non-sterile	Sterile/Non-sterile
Single Use or Reusable	Single-use (DSG™ Electronic T-handle and DSG™ Pin (active stylet)) Re-usable (Ratcheting Handle)	Single-use (DSG™ Electronic T-handle and DSG™ Pin (active stylet)) Re-usable (Ratcheting Handle, DSG™ Threaded Drill shaft and DSG™ Sleeve)
Distal Shaft Shape	Z-Direct Screw Driver shaft (K153404; reference device) and DSG™ Pin	Straight (cannulated) and DSG™ Pin
Dimensions	DSG™ Pin: 373mm x 1.65mm	DSG™ Pin: 373mm x 1.65mm; 292mm x 1.65mm Threaded Drill: 1.7mm inner diameter (hole) cannulated metal shaft with flanges (threads) and cutting edges; Thread outer diameters of 4.0, 5.5 and 8.0mm.

	DSG™ Zavation Screw System (*subject device*)	DSG™ Threaded Drill System (K152747)
Circuit Board	Capacitors, Resistors and Diodes - Firmware (programmable chip) on circuit board	Capacitors, Resistors and Diodes - Firmware (programmable chip) on circuit board

Performance Data

Performance testing for the subject device consisted of simulated insertion testing and cadaver testing to establish that the DSG™ Zavation Screw System is as safe and as effective as the predicate device to which it is a modification. All tests were passed, demonstrating equivalent performance according to device specifications and thus supporting substantial equivalence.

No animal or clinical tests were performed in support of this premarket notification.

Data supporting the labeling change that is the subject of this 510(k) notice is outlined below:

Test	Test Method Summary	Results
Cadaver Testing	Cadaveric usability testing was performed to demonstrate the usability and placement accuracy of the device.	Pass
Mechanical Testing	Mechanical testing was performed to demonstrate the performance and integrity of the system in implanting pedicle screws without a pilot hole.	Pass
Biocompatibility	Performed in accordance with ISO-10993	Pass
Sterilization Validation	EtO sterilization cycle designed and validated per NF EN ISO 11737-2	Pass
Electrical Safety	Performed in accordance with IEC 60601-1	Pass

Like its predicate, the SpineGuard DSG™ Zavation Screw System complies with the following recognized standards:

- ASTM F138-13, Standard specification for wrought 18 chromium-14 nickel-2.5 molybdenum stainless steel bar and wire for surgical implants (2013).
- ASTM F899-12b, Standard specification for wrought stainless steel for surgical instruments (2012).
- IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance, incl. Amendment 1 (2007).
- ISO 10993-5, Biological Evaluation of Medical Devices: Tests for in vitro cytotoxicity (2010).
- ISO 10993-7, Biological evaluation of medical devices: Ethylene Oxide sterilization residuals (2008).
- ISO 10993-10, Biological Evaluation of Medical Devices: Tests for irritation and sensitization (2010).
- ISO 10993-11, Biological Evaluation of Medical Devices: Tests for systemic toxicity (2009).

- ISO 11607-1, Packaging for terminally sterilized medical devices: Requirements for materials, sterile barrier systems and packaging systems (2006).
- ISO 11607-2, Packaging for terminally sterilized medical devices: Validation requirements for forming, sealing and assembly processes (2006).
- ISO 11737-1, Sterilization of medical devices - Microbiological methods: Determination of a population of microorganisms on products (2006).
- ISO 11737-2, Sterilization of medical devices - Microbiological methods: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (2010).
- ASTM D4169, Standard practice for performance testing of shipping containers and systems (2014).
- ASTM F1980, Standard guide for accelerated aging of sterile medical device packages (2011).
- ISO 11135-1, Sterilization of health care products - Ethylene oxide: Requirements for the development, validation and routine control of a sterilization process for medical devices (2007).

Conclusions

The DSG™ Zavation Screw System is as safe and effective as the predicate DSG™ Threaded Drill System (K152747). The subject device has the same intended use, and very similar indications for use, technological characteristics and principles of operation, as its predicate device. The minor technological differences between the DSG™ Zavation Screw System and its predicate device raise no new issues of safety or effectiveness. In addition, performance data demonstrate that the DSG™ Zavation Screw System is as safe and effective as the predicate device. Thus, the DSG™ Zavation Screw System is substantially equivalent.