



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 10, 2016

SpineGuard, S.A.
c/o Dr. John J. Smith
Hogan Lovells US LLP
555 13th Street, NW
Washington, DC 20004

Re: K152747

Trade/Device Name: SpineGuard DSG™ Threaded Drill System
Regulation Number: 21 C.F.R. §874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: II
Product Code: PDQ
Dated: May 9, 2016
Received: May 9, 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 yours,

**William J.
Heetderks -A**

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH,
ou=People,
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cn=William J. Heetderks -A
Date: 2016.06.10 13:50:34 -04'00'

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

Indications for Use

510(k) Number (if known)

K152747

Device Name

DSG™ Threaded Drill System

Indications for Use (Describe)

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™ Threaded Drill System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. 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.

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.

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510(k) SUMMARY

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

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: June 7, 2016

Name of Device

SpineGuard DSG™ Threaded Drill System

Common or Usual Name

Nerve Stimulator

Classification Name

21 C.F.R. §874.1820 Surgical Nerve Stimulator/Locator, PDQ

Predicate Devices

SpineGuard S.A., Cannulated PediGuard Nerve Detector (K143159)

Purpose of the 510(k) notice

The DSG™ Threaded Drill System is a modification to the cleared PediGuard System intended to add additional options for the surgeon to create pilot holes for pedicles screw systems.

Indication for Use

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™ 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.

Technological Characteristics

The DSG™ Threaded Drill System is designed to prepare pedicle screw holes. The sensor at the distal 3mm of the tip of the shaft detects the electrical impedance of the tissue immediately surrounding the sensor and provides real-time audio and visual information to the surgeon to assist the surgeon to determine the relative density of the tissue at the tip of the shaft. A skilled surgeon can interpret the varying pitch and cadence of the feedback to determine potential breaches of the cortical wall. The first 6mm at the tip of the instrument are very similar to the cleared PediGuard models, with a pointy awl type design to penetrate the bone. After that, a threaded portion of 25mm in length, featuring cutting flutes, allows for an easy insertion in bone. The threads allow for a smooth and progressive penetration in bone that results in steady and consistent readings of the impedance of the tissue, making the determination of potential breaches of the cortical wall easy for the surgeon.

Performance Data

The SpineGuard DSG™ Threaded Drill System was tested mechanically (bending tests of the shaft) to show the sensor characteristics were identical to the predicate devices. The detection performance of the new length of pins was also demonstrated to be equivalent to the predicates. In addition, the device durability was tested. Cleaning and sterilization validation demonstrated that the reusable components can be adequately cleaned and sterilized prior to reuse.

The SpineGuard DSG™ Threaded Drill 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 safety, Amendment 1 (2007).
- IEC 60601-1-4, Medical Electrical Equipment - Part 1-4: General requirements for safety, Collateral Standard: Programmable electrical medical systems, Edition 1.1
- 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 F88, Standard test method for seal strength of flexible barrier materials (2009).
- ASTM F1929, Standard test method for detecting seal leaks in porous medical packaging by dye penetration.
- 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 (2014).
- ISO 17665-1, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (2006).

Substantial Equivalence

The SpineGuard DSG™ Threaded Drill System has the same intended use and similar indications, principles of operation, and technological characteristics as the cleared PediGuard System. The minor differences in the DSG™ Threaded Drill System's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the SpineGuard DSG™ Threaded Drill System is substantially equivalent to the cleared PediGuard System.

| | Subject DSG™ Threaded Drill System (K152747) | Cannulated PediGuard® models (K143159) |
|------------------------------------|---|---|
| Intended Use / Indications for Use | <p>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.</p> <p>The DSG™ 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.</p> <p>The DSG™ Threaded Drill System also is specifically indicated for use in intraoperative electromyographic ("EMG")</p> | <p>The PediGuard® 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.</p> <p>The PediGuard System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. PediGuard is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine.</p> <p>The PediGuard also is specifically indicated for use in intraoperative electromyographic ("EMG") surveillance to assist in the</p> |

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|------------------------|---|---|
| | 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. | 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 |
| Components | Stainless Steel shaft, plastic handle, ceramic insulator, modular with removable handle, ratchet and reusable shaft | Stainless Steel shaft, plastic handle, ceramic insulator, modular with removable handle |
| Shaft Material | Inner electrode: 316L Stainless Steel (ASTM F138) Outer electrode and/or shaft: 304 Stainless Steel (ASTM F899), 316L Stainless Steel and/or 17-4PH (ASTM F899); Ceramic Zirconium Oxide Insulator | Inner electrode: 316L Stainless Steel (ASTM F138) Outer electrode and/or shaft: 304 Stainless Steel (ASTM F899), 316L Stainless Steel and/or 17-4PH (ASTM F899); Ceramic Zirconium Oxide Insulator |
| 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 |
| Single Use or Reusable | Single-use (T-Handle and Active Stylet) Re-usable (Ratcheting Handle, Threaded Drill Shaft and Sleeve) | Single Use |
| Distal Shaft Shape | Straight (cannulated) and active stylet | Straight (cannulated) with removable inner starter stylet (optional) and active stylet |
| Dimensions | 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. | Cannulated, inner diameter: 2.5mm; Tapered shaft outer diameter from 3 to 4mm. |
| Circuit Board | Capacitors, Resistors and Diodes - Firmware (programmable chip) on circuit board | Capacitors, Resistors and Diodes - Firmware (programmable chip) on circuit board |