February 10, 2021

SpineGuard, S.A.
℅ John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K201454
Trade/Device Name: DSG Connect Technology
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: PDQ, ETN
Dated: January 21, 2021
Received: January 21, 2021

Dear John 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201454

Device Name
DSG Connect Technology

Indications for Use *(Describe)*
PediGuard and PediGuard Cannulated systems:

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. 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. The PediGuard 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.

PediGuard Threaded System:

The PediGuard Threaded 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. PediGuard Threaded System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. PediGuard Threaded System is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine. PediGuard Threaded 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.

DSG Zavation screw system:

The 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 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.

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510(k) SUMMARY

DSG Connect Technology

I. Submitter

SpineGuard S.A.
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Contact Person: Stephane Bette

Date Prepared: June 1, 2020

II. Device

Name of Device: DSG Connect Technology

Common or Usual Name: Nerve Stimulator

Classification Name: 21 C.F.R. §874.1820 (Surgical Nerve stimulator/ locator)
Regulatory Class: Class II

Product Code: PDQ, ETN

III. Predicate Devices

K143159, PediGuard devices, SpineGuard SA
K143159, Cannulated PediGuard devices, SpineGuard SA
K152747, PediGuard Threaded systems, SpineGuard SA
K162884, DSG Zavation screw system, SpineGuard SA

IV. Device Description

The DSG Connect technology is a pedicle screw system used for bone drilling procedure during open or minimally invasive spinal fusion. The devices provide visual and audible alerts to a surgeon to indicate a change in electrical conductivity at the tip of the probe that may indicate contact of the tip with soft tissues. The DSG Connect Technology provides the user with an optional visual graphical presentation of the electrical conductivity information communicated by the DSG Connect devices to a tablet, with the App providing a visual representation of the audio signal emitted by the device handle. The App allows for display and recording of the signal, including graphing of changes in the audio signal over time.

The DSG Connect technology is incorporated in to the handles of the Cannulated PediGuard, PediGuard Threaded system, and DSG Zavation screw system.

V. Indications for Use

PediGuard and PediGuard Cannulated systems:

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. 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. The PediGuard 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.

PediGuard Threaded System:

The PediGuard Threaded 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. PediGuard Threaded System is indicated for use in both open and percutaneous (MIS) surgical approaches to the spine. PediGuard Threaded System is also indicated for use with fluoroscopic guidance in percutaneous (MIS) surgical approaches to the spine. PediGuard Threaded 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.

DSG Zavation screw system:

The 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 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.

VI. Comparison of Technological Characteristics With the Predicate Devices

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

- Integration of DSG Connect Technology
  - Modification of electronics board to include wireless transmitter
  - Added Connect App using commercial tablet as Hardware platform (Microsoft Go)
- Hardware changes
  - Change of audio technology (speaker→ buzzer)
  - Change of integration of low battery threshold detection into design
  - Changes to some electronic components, manufacturing process & configuration of board
  - Change in electronic component for device activation (replacement of legacy electronic contact blade, PediGuard device only)
  - Added BLE communication module (Bluetooth)
- Software changes
  - Addition of low battery threshold detection
  - Monitoring of new parameters (battery voltage, reference voltage, microcontroller (MCU) temperature)
  - Added firmware to manage BLE transmission of data pushed by MCU

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

- Electrical safety in accordance with IEC 60601-1
- Electromagnetic compatibility in accordance with IEC 60601-1-2
- Wireless coexistence

Name	Description
Autonomy test	Verify the autonomy of the modified electronics
Impaction, weight and cap resistance test	Verify the mechanical resistance of the plastic casing with the modified inner geometry
Low-battery mode verification and re-usage prevention	Verify the correct implementation of the low battery detection and the reusage prevention feature in the modified electronics / embedded software
Pulse output	Verify that the electrical pulse is sent within the specifications in terms of duration / frequency / intensity
Output signal evaluation	Verify that the output signal of the modified device (modified electronics / embedded software) is equivalent to the predicate device for similar conductivity levels
Sound evaluation	Verify that the sound volume of the modified device (using a buzzer) is at least equivalent to the predicate device (using a speaker)

System Evaluation	System design validation by surgeon in a pig lab
Bluetooth communication	Verify the proper connection between the devices and that the data transferred and displayed on the tablet are correct
Safety features	Verify the correct implementation of the various safety features in the modified electronics / embedded software (LED and buzzer status when device is on in air, on in conductive medium, on with shortcut, on with low battery and off)
DSG Connect App GUI verification	Design verification of the DSG Connect App Graphic User Interface (GUI)
Maximum regulated pulse output	Verify that the maximum current that is sent into the patient is within the specifications and as per the predicate device (below 5.5mA)
Curve smoothing / Amplification	Memo on the data treatment to ensure the signal is displayed adequately

VIII. Conclusions

The DSG Connect family of products are comparable to the predicate PediGuard devices, Cannulated PediGuard, PediGuard Threaded, and DSG Zavation Screw systems, with the technological differences in comparison to the predicate devices not raising new or different questions of safety and effectiveness. Additionally, the non-clinical data support the safety and effectiveness of the DSG Connect family of systems when used as intended in the specified use conditions.