

K123390

AUG 8 2013

510(k) SUMMARY

SpineGuard's PediGuard® 2.5mm XS (model P1-AU414), PediGuard® Curv XS model (P1-U451) and Cannulated PediGuard Needle#2 model (P2ND1002)

Submitter:

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Date Prepared: July 30, 2013

Name of Device:

PediGuard 2.5mm XS (Model P1-AU414)
PediGuard Curv XS (Model P1-AU451)
Cannulated PediGuard Needle#2 (Model P2ND1002)

| | |
|-----------------------|-----------------------------------|
| Common or Usual Name: | Nerve Stimulator |
| Classification Name: | Surgical Nerve Stimulator/Locator |
| Review Panel: | Neurology |
| Product Code: | PDQ and ETN |
| Device Class: | Class II |
| Regulation: | 21 C.F.R. §874.1820 |

Predicate Devices

SpineGuard S.A., PediGuard Nerve Detector (K030526)

Device Description

The PediGuard® 2.5mm XS and PediGuard® Curv XS are single use, single piece devices composed of stainless steel and plastic that are provided sterile, and consist of a handle containing the electronics and a stainless steel shaft with distal sensor for measuring electrical impedance of the tissues immediately in contact with the sensor during use. The devices product visual and audible signal to indicate changes in impedance associated with possible vertebral perforation.

The Cannulated PediGuard® Needle #2 is the needle part of a single-use modular device provided sterile, consisting of a handle containing the electronics, a stainless steel cannulated outer shaft and a stainless steel inner sensor needle for measuring electrical impedance of the tissues immediately in contact with the sensor during use.

PediGuard® 2.5mm XS (model P1-AU414), PediGuard® Curv XS (model P1-AU451) and Cannulated PediGuard® Needle#2 (model P2ND1002) provide real-time visual and auditory feedback to the surgeon during the preparation of the pedicle screw pilot holes, sounding an alert when the tip of the sensor senses a change in the impedance of the surrounding tissues, which may indicate that the tip is in contact with soft tissues and a possible vertebral cortex perforation.

Intended Use/Indications for Use

The PediGuard® 2.5mm XS (model P1-AU414), PediGuard® Curv XS (model P1-AU451) and Cannulated PediGuard® Needle#2 (model P2ND1002) are 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 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.

Substantial Equivalence

The PediGuard® 2.5mm XS (model P1-AU414), PediGuard® Curv XS (model P1-AU451) and Cannulated PediGuard® Needle#2 (model P2ND1002) have the same intended use/indications for use, and similar technological characteristics and principles of operation as the cleared PediGuard Nerve Detector. The materials in the modified devices are directly comparable to the predicate and the impedance detection algorithm is identical. The minor differences in shaft diameter, shaft materials or electronics (firmware and power source) do not raise any new questions of safety or effectiveness. Performance data that evaluated static bending, electrical signal emission, impedance detection actability and the ability to convey changes in impedance to the user demonstrate that the PediGuard® 2.5mm XS (model P1-AU414), PediGuard® Curv XS (model P1-AU451) and Cannulated PediGuard® Needle#2 (model P2ND1002) are as safe and effective as the cleared PediGuard Nerve Detector. Thus, the PediGuard® 2.5mm XS (model P1-AU414), PediGuard® Curv XS (model P1-AU451) and Cannulated PediGuard® Needle#2 (model P2ND1002) are substantially equivalent to the predicate device.

Substantial Equivalence Chart

| | | | |
|--|--|---|---|
| | SpineGuard Cleared Device PediGuard (K030526) | PediGuard® 2.5mm XS (P1-AU414) PediGuard® Curv XS (P1-AU451) | Cannulated PediGuard Needle#2 (P2ND1002) |
|--|--|---|---|

| | | | |
|------------------------------------|--|--|--|
| Intended Use / Indications for Use | The SpineGuard, <i>PediGuard Nerve Detector System</i> 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 <i>PediGuard</i> 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. | The <i>PediGuard</i> ® 2.5mm XS (model P1-AU414), and <i>PediGuard</i> ® Curv XS (model P1-AU451) are 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 <i>PediGuard</i> 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. | The <i>PediGuard</i> ® Cannulated <i>PediGuard</i> ® Needle#2 (model P2ND1002) 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 <i>PediGuard</i> 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 | Straight – screwdriver | Gearshift T-Handle | T-handle |
| Components | Single Piece or Modular, Stainless-Steel shaft, plastic handle, PEEK insulator | Single Piece, Stainless Steel shaft, plastic handle, ceramic insulator | Modular unit with Cannulated outer shaft, active sensory needle, and ceramic insulation |
| Shaft Material | Inner electrode: 316L Stainless Steel (ASTM F138) Outer electrode: 316L Stainless Steel (ASTM F138) | Inner electrode: 316L Stainless Steel (ASTM F138) Outer electrode or shaft: 316L Stainless Steel and/or 17-4PH (ASTM F899) | Inner electrode: 316L Stainless Steel (ASTM F138) (Electrode) Outer electrode and shaft: 304 Stainless steel (ASTM F899) |
| 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. | Device cannot be turned off until battery exhausted. Prevents reuse of device. |
| Power Source | Silver Oxide Battery | Lithium-Ion Battery | Lithium-Ion Battery |
| Sterility | Sterile | Sterile | Sterile |
| Single Use or Reusable | Single-use | Single-use | Single-use |
| Distal Shaft shape | Straight | Curved or straight | Straight with removable inner starter stylet (optional) and sensory needle. |
| Dimensions | 3.2mm and 4.0 mm shaft diameter | 2.5mm shaft diameter / tapered for 2mm to 4mm | 3.0mm shaft diameter |
| Circuit board | Capacitors, Resistors and Diodes | Capacitors, Resistors and Diodes - Firmware (programmable chip) on circuit board | Capacitors, Resistors and Diodes - Firmware (programmable chip) on circuit board |

Biocompatibility

Biocompatibility testing was conducted on the *PediGuard*® models in accordance with the testing recommendations in ISO 10993 -1 (Biological Evaluation of Medical Devices Part 1: Evaluation and Testing) and the FDA's Blue Book Memorandum # G95-1 for a device in limited (≤ 24 hours) contact with tissue/bone. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. The tests and results are summarized in the table below.

| Tests | Results ¹ | Conclusion ¹ |
|--|------------------------------|-------------------------|
| <i>In vitro</i> Cytotoxicity test (ISO MEM Elution assay with quantitative evaluation of cytotoxicity) – ISO 10993-5 | No evidence of cytotoxicity | Non-cytotoxic |
| Intracutaneous Reactivity test (irritation) – ISO 10993-10 | No evidence of irritation | Non-irritant |
| Sensitization test (Guinea pig maximization) – ISO 10993-10 | No evidence of sensitization | Non-sensitizing |
| Acute Systemic Toxicity test – ISO 10993-11 | No signs of toxicity | Not systemically toxic |

¹Separate biocompatibility testing was conducted for the PediGuard Curv, PediGuard Curv XS, and the Cannulated PediGuard models. Results and conclusions are summarized for all three models unless otherwise noted.

As shown in the table, biocompatibility testing found the PediGuard® models to be non-cytotoxic, non-irritating, non-sensitizing, and non-toxic (acute systemic).

Performance Data

Static bending testing was performed on the shafts. All device models performed as intended in a manner directly comparable to the predicate devices. All device models have completed firmware verification and validation testing. The PediGuard® models conform to the following standards:

- ASTM F138-08, Standard specification for wrought 18 Chromium – 14 Nickel – 2.5 Molybdenum Stainless Steel Bar and Wire for surgical implants (UNS S31673) (Version 8) (2008).
- ASTM F899-1, Standard specification for wrought stainless steel for surgical instruments (Version 11) (2009).
- IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for safety, Amendment 1, Amendment 2.
- 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 (1999).
- ISO 10993-10, Biological Evaluation of Medical Devices: Tests for irritation and sensitization.
- ISO 10993-11, Biological Evaluation of Medical Devices: Tests for systemic toxicity.
- 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).

- ISO 10993-7, Biological evaluation of medical devices: Ethylene Oxide sterilization residuals (2008).
- 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 (2000).
- 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).
- 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 (2007).
- ASTM D4169, Standard practice for performance testing of shipping containers and systems (2005).

In addition to these standards, testing was conducted on the devices to demonstrate that the electrical signal emitted by the modified PediGuard was directly comparable to that of the predicate. The ability to measure changes in impedance and the volume of the audible signal emitted by the device were also measured and found to be directly comparable.

The following design verification and validation testing was performed to support the substantial equivalence of the modification to the original predicate performance levels: Surgeon testing, Bending tests, Sensor Testing, Drill durability testing, Compliance with ASTM standards, Compliance with biocompatibility standards, 100% testing of firmware, Battery function testing, and Destructive testing.

Conclusion

The comparison to the predicate devices demonstrates that the PediGuard® 2.5mm XS (model P1-AU414), PediGuard® Curv XS (model P1- AU451) and Cannulated PediGuard® Needle#2 (model P2ND1002) are safe and effective for its intended use and are substantially equivalent to the predicate devices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

August 8, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-G609
Silver Spring, MD 20993-0002

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

Re: K123390

Trade/Device Name: PediGuard 2.5mm XS (Model P1-AU414)
PediGuard Curv XS (Model P1-AU451)
Cannulated PediGuard Needle#2 (Model P2ND1002)

Regulation Number: 21 C.F.R. §874.1820

Regulation Name: Neurosurgical Nerve Locator

Regulatory Class: Class II

Product Code: PDQ and ETN

Dated: November 2, 2012

Received: December 11, 2012

Dear Mr. 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

Page 2 - Mr. John J. Smith

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting 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): K123390

Device Name: PediGuard 2.5mm XS (Model P1-AU414)
PediGuard Curv XS (Model P1-AU451)
Cannulated PediGuard Needle#2 (Model P2ND1002)

Indications For Use:

The PediGuard® 2.5mm XS (model P1-AU414), PediGuard® Curv XS (model P1-AU451) and Cannulated PediGuard® Needle#2 (model P2ND1002) are 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 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.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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| <p>Joyce M. Whang -S</p> <hr/> <p>(Division Sign Off) Division of Neurological and Physical Medicine Devices (DNPMD)</p> <p>510(k) Number <u> K123390 </u></p> |
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