September 26, 2024

SpineGuard
℅ John Smith
Partner
Hogan Lovells US LLP
555 13th Street NW
Washington, District of Columbia 20004

Re: K241895
Trade/Device Name: Cannulated PsiFGuard
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: SCY
Dated: June 28, 2024
Received: June 28, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHANIE SMITH -S

For Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K241895

Device Name
Cannulated PsiFGuard

Indications for Use *(Describe)*
The Cannulated PsiFGuard is an accessory to systems intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. It is indicated for use during sacroiliac joint guidewire placement to provide feedback to the surgeon via visual and audible alerts that indicate a change in conductivity at the tip of the probe and may indicate contact of the tip with bone and possible cortex perforation.

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 Cannulated PsiFGuard

Submitter: SpineGuard S.A.
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Contact Person: Stephane Bette

Date Prepared: September 23, 2024

Name of Device: Cannulated PsiFGuard

Common or Usual Name: Sacroiliac joint guidewire placement device

Classification Name: 21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II

Product Code: SCY

Predicate Devices

K221047 SILO TFX MIS Sacroiliac Joint Fixation System

Reference Devices

K201454 Cannulated PediGuard with DSG Connect technology, SpineGuard S.A.

Device Description

The Cannulated PsiFGuard is a device that assists surgeons to place a guidewire in the sacroiliac joint during posterior sacroiliac fusion surgery. The Cannulated PsiFGuard device serves to alert the surgeons prior to a possible cortex perforation during guidewire placement, by analyzing the electrical conductivity of the surrounding tissues. The Cannulated PsiFGuard consists of a stainless steel needle component and electronic handle (DSG Handle or the DSG Connect Handle).

The Cannulated PsiFGuard has exactly the same principles of operation as the previously cleared systems, i.e. the tip of the instrument simultaneously penetrates the tissue for guidewire placement and senses possible cortex perforation or contact with bone. The devices then provide a visual and audible feedback to the surgeon to indicate changes in conductivity associated with possible bone perforation. If the DSG Connect handle is used, the device also allows for the signal generated by the device to be transferred to a tablet, to visually reproduce the audio signal over time.

Intended Use / Indications for Use

The Cannulated PsiFGuard is an accessory to systems intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. It is indicated for use during sacroiliac joint guidewire placement to provide feedback to the surgeon via visual and audible alerts that indicate a change in conductivity at the tip of the probe and may indicate contact of the tip with bone and possible cortex perforation.

Summary of Technological Characteristics

The subject device is similar to instruments from the predicate instrument, It is an elongated instrument to penetrate the joint in preparation of guidewire placement.

The subject device adds the electrical conductivity sensing to the instrumentation from the predicate. The technological characteristics of the subject device are identical to the listed reference device. The subject device has the same design, and the changes will be limited to the labeling to reflect the new indications for use.

Performance Data

The Cannulated PsiFGuard was evaluated in a cadaver study to demonstrate sacroiliac joint guidewire placement accuracy when using the Cannulated PsiFGuard in comparison to standard technique and its ability to measure tissue impedance.

The mechanical performance of the Cannulated PsiFGuard was also evaluated under cantilever bending loads to demonstrate the device can withstand the mechanical action induced by sacroiliac joint guidewire placement.

In all instances, the Cannulated PsiFGuard functioned as intended and the performance observed was as expected.

Conclusions

The Cannulated PsiFGuard and the predicate device have similar intended use, indications, technological characteristics and principles of operation. The only differences are due to the function of the subject device, which is limited to the placement of guidewires during the posterior sacroiliac fusion procedure, with additional step in the surgical procedure to include technological features for enhanced safety. These differences do not present different questions of safety or effectiveness, and only improve the safety in achieving the indications for use of the predicate device. Thus, the Cannulated PsiFGuard is substantially equivalent to the instruments from the predicate device.