August 2, 2019

SpineWelding AG
% Ms. Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K183091
Trade/Device Name: Elaris Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: July 2, 2019
Received: July 2, 2019

Dear Ms. Hogan:

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,

Ronald P. Jean, Ph.D.
Assistant 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 on last page*

510(k) Number *(if known)*
K183091

Device Name

**Elaris Pedicle Screw System**

Indications for Use *(Describe)*

The Elaris Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments through posterior, non-cervical, pedicle fixation in skeletally mature patients as an adjunct to fusion in the treatment of the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. The Elaris Pin polymer can be ultrasonically deposited through the Elaris Pedicle Screw in skeletally mature patients as an adjunct to fusion for the indications listed above.

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**
**SpineWelding's Elaris Pedicle Screw System**

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

SpineWelding AG
Wagistrasse 6
Schlieren, Switzerland
Phone: +41 44 204 61 21
Facsimile: +41 44 204 61 20
Contact Person: Joerg Mayer, Managing Director, CTO

Date Prepared: August 2, 2019

**Name of Device and Name**

Elaris Pedicle Screw System

**Common or Usual Name**

Thoracolumbosacral pedicle screw system (NKB), class II

**Classification Name**

Thoracolumbosacral pedicle screw system (21 CFR 888.3070)

**Predicate and Reference Devices**

- K170347, Medtronic's CD Horizon Pedicle Screw System (Primary Predicate)
- K171228, SportWelding Fiji Anchor (Reference Device)
- K073439, Globus Medical Transition Stabilization System (Reference Device)

**Indications for Use**

The Elaris Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments through posterior, non-cervical, pedicle fixation in skeletally mature patients as an adjunct to fusion in the treatment of the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. The Elaris Pin polymer can be ultrasonically deposited through the Elaris Pedicle Screw in skeletally mature patients as an adjunct to fusion for the indications listed above.

**Technological Characteristics**

The ELARIS Pedicle Screw System consists of the following components: Elaris Pedicle Screws, Elaris Pins, Elaris Rod, Elaris Set Screw, Dedicated Manual Instruments, and an Ultrasonic System, which includes the ultrasonic generator (BoneWelder 150-W1) with corresponding footswitch and power cord, and the spring loaded Elaris Handpiece with the Elaris Connector, which rigidly couples the housing of the Elaris Handpiece with the Elaris Pedicle Screw.

The cannulated pedicle screws are available in two diameters and four lengths and contain a distal fenestration to optionally allow injection of resorbable polymer into the cancellous bone of the vertebral body. The Ti alloy screws are multiaxial, and are rigidly attached to the rods via the set screw. The Elaris Pin can intraoperatively be inserted into the screws cannulation. The Elaris handpiece can be

connected to the pedicle screw head, and using the BoneWelder, the polymer is ultrasonically heated so that it melts and is extruded out of the fenestrations.

**Performance Data**

The following tests were performed to demonstrate the substantial equivalence of the Elaris Pedicle Screw:

- IEC 60601-1 and 60601-1-2 testing of the handpiece
- Static and dynamic axial compression testing and torsion testing per ASTM F1717
- Dynamic screw pull out testing to assess effect of polymer enhancement
- Dynamic toggle testing to assess effect of polymer enhancement
- Polymer characterization testing (before and after melting and throughout degradation)
- Temperature distribution characterization during polymer enhancement
- Screw removal testing
- Cavitation risk assessment
- Polymer swelling risks assessment
- Polymer flow distance analysis
- FEA of screw loading with distal fixation
- Spine fusion animal study to assess bioresponse to Elaris
    - Dynamic screw pullout testing
    - Screw removal testing

**Comparison to the Predicate Device**

The Elaris Pedicle Screw that is part of the subject system falls within the range of cleared screw sizes marketed for the CD Horizon Legacy Spinal System (see comparison table below). The screws in both spinal systems are comprised of the same material. In addition, the Elaris Pedicle Screw and the predicate screws are inserted manually using standard surgical techniques for pedicle screws. While the Elaris Pedicle Screw utilizes a bioresorbable polymer forming a solid ring-like interface around the tip of the screw designed for initial enhanced fixation, the predicate spinal system uses hydroxyapatite ("HA") on certain components as a means of enhanced fixation. In addition, FDA has cleared numerous pedicle screws coated with HA to enhance the fixation of pedicle screws in the spine and thus, increase the pull out resistance of these screws.

With regard to the method of insertion, the subject device differs slightly from the CD Horizon in that the predicate implant relies solely on thread fixation in bone. In contrast, the subject system is comprised of a titanium alloy pedicle screw and, optionally, a bioresorbable polymer (PLDLLA) pin in which the simultaneous activation of ultrasonic energy and automated (spring-loaded) axial movement of the handpiece result in the temporary, local, and controlled melting of the polymer at the tip of the Elaris Pedicle Screw. During this process, the polymer infiltrates the three dimensional, superficial bone structures adjacent to the Elaris Pedicle Screw and, following a rapid solidification due to immediate cooling, forms a strong initial interface between the tip of the Elaris Pedicle Screw and the adjacent bone. Thus, the Elaris Pedicle Screw optionally relies on an additional polymeric component designed to enhance initial fixation, whereas the predicate CD Horizon relies on thread fixation only. While this and the other minor differences outlined above could affect the safety and effectiveness, these differences do not raise new questions of safety and effectiveness. Rather, the subject system and the predicate device raise the same questions with regard to method of pedicle screw insertion, stability of screws, and bioresponse to implants.

Any risks associated with the device are not new risks to pedicle screw systems as damage to bone or soft tissue is always possible due to misplaced screws as is adverse biological reactions. The

company has performed animal testing to assess these risks and the completed testing demonstrates that the device has an equivalent benefit risk profile as cleared predicate devices.

Testing per ASTM F1717 for lumbar systems has demonstrated equivalent mechanical strength to cleared pedicle screw systems. The polymer used in the device has been characterized and verified that it is not significantly altered by melting. Bench testing has demonstrated that the polymer enhancement provides improved dynamic pullout strength out to 52 weeks as well as improved resistance to toggle loosening. Finally, testing has also demonstrated that the screws can be safely removed after polymer enhancement.

| | **SpineWelding Elaris Pedicle Screw System** | **Medtronic CD Horizon** |
|---|---|---|
| **510(k)** | **Subject** | **K170347** |
| **Components** | Fenestrated, cannulated, polyaxial pedicle screws<br>Metallic rods<br>Elaris Pin<br>BoneWelder + Handpiece | Fenestrated, cannulated, polyaxial pedicle screws<br>Metallic rods |
| **Pedicle Screw Size** | 6.5 – 7.5 mm diameter<br>40 – 60 mm length | 4.5 – 10.5 mm diameter<br>30 – 100 mm length |
| **Rod Lengths** | 40 – 100 mm, 350 mm | Unknown |
| **Insertion Method** | Rotate screw into pilot hole | Rotate screw into pilot hole |
| **Fixation Method** | Screw threads in bone,<br>Optionally, polymer enhancement | Screw threads in bone |
| **Length of ultrasound energy delivery** | Not more than 8 seconds | N/A |
| **Implant Material** | Ti alloy<br>PLDLLA (pin) | Ti alloy, CoCr |
| **Resorbable** | Partly | No |
| **Sterilization** | Sterile (pin)<br>Non-sterile (all other components) | Sterile (cement)<br>Non-Sterile (screws) |

**Conclusions**

The Elaris Pedicle Screw System performs as intended and is substantially equivalent to the predicate device.