February 13, 2024

Signature Orthopaedics Pty Ltd
Declan Brazil, Ph.D.
Managing Director
7 Sirius Road
Lane Cove West, NSW 2066
Australia

Re: K231134
Trade/Device Name: VerteLoc Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR
Dated: November 30, 2023
Received: January 12, 2024

Dear Dr. Brazil:

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.

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,

Brent Showalter -S

Brent Showalter, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231134

Device Name
VertLoc Spinal System

Indications for Use *(Describe)*
The VerteLoc Spinal System is indicated for use as a cervical vertebral body replacement (VBR) fusion device in the cervical spine (C3-C7) in skeletally mature patients for partial or total replacement of diseased, collapsed, damaged or unstable vertebral body due to tumour, trauma (i.e., fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues.

The VerteLoc Spinal System is to be used with bone graft material. The VerteLoc Spinal System is intended for use with supplemental internal fixation that has been cleared by the FDA.

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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5 510(K) SUMMARY

Manufacturer:

Signature Orthopaedics Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Australia

Signature Orthopaedics Europe Ltd
Unit A, IDA Business & Technology Park Garrycastle
Athlone Westmeath N37 DY26
IRELAND

Device Trade Name: Verteloc Spinal System

Common Name: Vertebral Body Replacement Device – Cervical

Contact:

Dr. Declan Brazil
Managing Director of Signature Orthopaedics

Prepared By:

Signature Orthopaedics Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Australia
Phone: +61 (2) 9428 5181
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Date Prepared: Monday, October 9, 2023

Classification: Class II as per 21 CFR 888.3060 Spinal Vertebral Body Replacement Device (PLR)

Predicate Devices:

Primary Predicate Device

- DePuy Synthes Spine Bengal Stackable Cage System (K190284)

Reference Predicate Devices

- K2M Santorini Corpectomy Cage Systems (K180665)
- Signus Medizintechnik GmbH Athlet VBR System (K081332)
- Signature Orthopaedics Arlington Cage (K172020)

Device Description:

The Verteloc Spinal System is a modular vertebral body replacement (VBR) system intended to replace a diseased, collapsed, damaged or unstable cervical vertebral body following partial or total corpectomy. The VerteLoc device comprise of three components; two end bodies and one mid body, which when used in combination is used to replace a measured deficit in the patient's spine. The VerteLoc device is offered in a variety of footprints and heights to accommodate the needs of patients.

When assembled, the central portion of the end and mid bodies create an inner hollow for the placement of autograft and/or autograft bone graft material. The VerteLoc device is manufactured from unreinforced PEEK OPTIMA LT1 as per ASTM F2026 with titanium pins as per ASTM F136 and ISO 5832-3 as well as tantalum marker beads as per ASTM F560 and ISO 13782.

The VerteLoc Spinal System VBR is to be used in conjunction with supplemental fixation systems.

Indications for Use:

The VerteLoc Spinal System is indicated for use as a cervical vertebral body replacement (VBR) fusion device in the cervical spine (C3-C7) in skeletally mature patients for partial or total replacement of diseased, collapsed, damaged or unstable vertebral body due to tumour, trauma (i.e., fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues.

The VerteLoc Spinal System is to be used with bone graft material. The VerteLoc Spinal System is intended for use with supplemental internal fixation that has been cleared by the FDA.

Summary of Technological Characteristics:

The VerteLoc Spinal System share the following technological characteristics as the predicate devices:

- The VerteLoc Spinal System has the same intended use as the DePuy Synthes Bengal Stackable Cage System.
- The VerteLoc Spinal System has a shared indications for use as the DePuy Synthes Bengal Stackable Cage System.
- The VerteLoc Spinal System Cages are manufactured from the same material as the DePuy Synthes Bengal Stackable Cage System as well as Signature Orthopaedics Arlington Cages with the exception of the titanium pins.
- The VerteLoc Spinal System Cages have the same height range as the DePuy Synthes Bengal Stackable Cage System and has the available length and widths fall within the Depuy Synthes Bengal Stackable Cage System' range.
- The Verteloc Spinal System Cages are packaged, transported and sterilised through the same method(s) as Signature Orthopaedics Arlington Cages.

The following are the technological differences between the VerteLoc Spinal System and the predicate devices:

- The VerteLoc Spinal Cage utilises titanium pins to assist in initial fixation where the Depuy Synthes Bengal Stackable Cage System does not include additional titanium pins and utilises the surface finish on the outer cages top and bottom surface areas (the same as the subject device) only.
- The VerteLoc Spinal Cage utilises a snap-fit lock between stackable cages where as the DePuy Synthes Bengal Stackable Cage System uses screw and nut fasteners.

Performance Data:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Verteloc Spinal System is adequate for anticipated in-vivo use. No animal or clinical testing was required to support substantial equivalence. Non-clinical testing carried out included:

- Static Axial Compression Testing
- Static Torsional Testing
- Dynamic Axial Compression Testing
- Dynamic Torsional Testing
- Subsidence Testing

The results of verification and validation analyses demonstrated the Verteloc Spinal System to be substantially equivalent to the predicate devices.

Conclusion:
The subject devices are substantially equivalent to the predicate devices since it has the same intended use, indications for use, materials, design features, and sterilisation to either all or one of the predicate devices. Non-clinical testing support the substantial equivalence claim.