December 7, 2018

Signature Orthopaedics Pty Ltd.
Declan Brazil
Managing Director
7 Sirius Road
Lane Cove, 2066 AU NSW

Re: K180754
Trade/Device Name: C-Zero Pedicle Screw System, Freedom Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw Systems
Regulatory Class: Class II
Product Code: NKB
Dated: October 31, 2018
Received: November 5, 2018

Dear Declan 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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'neill -S for MNM

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180754

Device Name
C-Zero Pedicle Screw System, Freedom Pedicle Screw System

Indications for Use *(Describe)*
The Signature Orthopaedic C-Zero Pedicle Screw System and Freedom Pedicle Screw System are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities and deformities of the thoracic, lumbar, and sacral spine: 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 and/or lordosis); tumor; and failed previous fusion (pseudarthrosis). In addition, the C-Zero Pedicle Screw and Freedom Pedicle Systems are intended for skeletally mature patients in the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra and degenerative spondylolisthesis with objective evidence of neurologic impairment.

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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2 510(K) SUMMARY

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

Device Trade Name:
C-Zero Pedicle Screw System
Freedom Pedicle Screw System

Common Name:
Pedicle screw spinal system

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:
October 31st, 2018

Classification:
Class II per 21 CFR 888.3070: Thoracolumbosacral Pedicle Screw System (NKB)

Predicate Devices:

Primary Predicate
- DePuy Synthes's EXPEDIUM 4.5mm Spine System (K081252)

Additional Predicate
- INTERPORE CROSS International Synergy Spinal Systems (K041449)
- Spinal Concepts' InCompass Spinal Fixation System (K023644)
- K2M Mesa Spinal System (K052398)
- Back to Basic Dymaxeon Spine System (K150184)

Reference Predicate
- Signature Orthopaedics NOOSA ALIF Plate (K163625)
- Signature Orthopaedics CoCr Femoral Head (K121297)

Device Description:

All of the Signature Orthopaedics' C-Zero and Freedom Pedicle Screw Systems' components (except for CoCr longitudinal rods) are manufactured from Ti6Al4V alloy per ISO 5832-3 and ASTM-F136. The subject systems' CoCr longitudinal rods are manufactured from wrought Cobal-Chromium as per ASTM-F1537.

The Signature Orthopaedics' C-Zero and Freedom Pedicle Screw Systems are used to

provide immobilization and stabilization of spinal segments in the treatment of acute and chronic instabilities or deformities of the lumbar, thoracic and sacral spine. These pedicel rod and screw systems surgically implanted from a posterior approach. The device subject to this file include polyaxial pedicle screws, rods, connectors and hooks.

Indications for Use:

The Signature Orthopaedic C-Zero Pedicle Screw and Freedom Pedicle Screw Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities and deformities of the thoracic, lumbar and sacral spine: 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 and/or lordosis); tumor; and failed previous fusion (pseudarthrosis). In addition, the C-Zero Pedicle Screw and Freedom Pedicle Systems are intended for skeletally mature patients in the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra and degenerative spondylolisthesis with objective evidence of neurologic impairment.

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of the Signature Orthopaedic C-Zero Pedicle Screw System and Freedom Pedicle Screw System are adequate for anticipated in-vivo use. The following non-clinical testings were carried out on the worst case sizes of the subject pedicle screws:

- Static and dynamic compression bending testing
- Static torsion testing
- Static Flexion-Extension Moment Test
- Axial Gripping Test
- Axial Torsional Test
- Axial Gripping Test of connector components
- Torsional Gripping Test of connector components
- Screw insertion testing
- Screw pull-out testing
- Screw torque to failure testing
- Freedom Dissociation Test at the screw-tulip interface

Testing Standards:

- **ASTM-F1717**_Standard Test Methods for Spinal Implant Construct in a Vertebrectomy Model
- **ASTM-F1798-13**_Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
- **ASTM-F543**_Standard Specification and Test Method for Metallic Medical Bone Screw

Substantial Equivalence:

The substantial equivalence of the subject devices to the predicate devices above is based

upon the similarity of intended use, design (fundamental scientific technology), materials and performance.

Comparison of technological characteristics

The Signature Orthopaedics C-Zero and Freedom Pedicle Screw Systems were bio-mechanically tested and compared to other predicate systems currently on the market. The design features and sizing of the components were also compared to the predicate devices and found to be substantially the same as these systems. The substantial equivalency between the subject and predicate devices were established based on the following similarities:

- The same indication for use
- The same range of intended surgery sites
- Manufactured from similar materials
- Similar in most of design features
- Similar Surgical Techniques
- Similar size range

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

- Some of design features detail
- Cap Screw diameters
- Varieties of tulip offered

Conclusion

Based upon the predicate comparison, the intended use, similar technological characteristics and the results of the various mechanical testing, the proposed devices are substantially equivalent to the predicate devices.