January 17, 2019

Signature Orthopaedics Pty Ltd.
% Dr. Declan Brazil
Managing Director
7 Sirius Road
Lane Cove, New South Wales 2066
AUSTRALIA

Re: K181190
Trade/Device Name: Pinehurst Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 19, 2018
Received: December 26, 2018

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 (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,

Ronald P. Jean -S

for 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)*
K181190

Device Name
Pinehurst Anterior Cervical Plate System

Indications for Use *(Describe)*

The Signature Orthopaedics Pinehurst Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilisation and stabilisation of the spine as an adjunct to fusions in patients with:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- Spondylolisthesis;
- Trauma (I.e fracture or dislocations);
- Tumors;
- Deformity (defined as kyphosis, lordosis, or scoliosis);
- Pseudoarthrosis;
- Failed previous fusion;
- Spinal stenosis

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:
Pinehurst Anterior Cervical Plate System

Common Name:
Spinal Intervertebral Body Fixation Orthosis

Contact:
Dr. Declan Brazil
Managing Director of Signature Orthopaedics

Prepared By:
Signature Orthopaedics Pty Ltd
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Lane Cove, NSW 2066
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Date Prepared:
April 30th, 2018

Classification:
Class II per 21 CFR 888.3060: Spinal Intervertebral Body Fixation Orthosis (KWQ)

Predicate Devices:

Primary Predicate

- L&K Biomed LnK Anterior Cervical Plate System (K143279)

Additional Predicate

- Spinal Concepts SC-AccFix Thinline Anterior Cervical Plate System (K013979)
- Orthofix CETRA Anterior Cervical Plate System (K162638)
- Globus Medical PROVIDENCE Anterior Cervical Plate System (K070775)
- DePuy Synthes CSLP System (K945700, K000536, K000742, K030866)
- Signature Orthopaedics NOOSA Anterior Lumbar Plate System (K163625)

Device Description:

The Signature Orthopaedics' Pinehurst Anterior Cervical Plate System's components are manufactured from Ti6Al4V alloy per ISO 5832-3 and ASTM-F136.

The Pinehurst Anterior Cervical Plate Systemis temporary supplemental fixation device consisting of variety of shapes and sizes of plates and screws. The plates attach to the anterior cervical spine with a minimum four screw per plate. The plates are offered in

one-level, two-level, three-level and four-level fusion configurations. The plates have an integrated locking mechanism that prevents screw-backout. The Pinehurst plates and screws are supplied sterile.

Indications for Use:

The Signature Orthopaedics Pinehurst Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilisation and stabilisation of the spine as an adjunct to fusions in patients with:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- Spondylolisthesis;
- Trauma (I.e fracture or dislocations);
- Tumors;
- Deformity (defined as kyphosis, lordosis, or scoliosis);
- Pseudoarthrosis;
- Failed previous fusion;
- Spinal stenosis

Performance Testing:

Non-clinical testing and engineering evaluations were conducted to verify that the performance of Pinehurst Anterior Cervical Plate System is adequate for anticipated in-vivo use. The following non-clinical testings were carried out on the worst case sizes of the plates and screws:

- Static and dynamic compression bending testing
- Static torsion testing
- Screw insertion testing
- Screw pull-out testing
- Screw torque to failure testing

Substantial Equivalence:

That Signature Orthopaedics' Pinehurst Anterior Cervical Plate System have the same intended use, indication for use, materials and similar design features as the Spinal Concepts SC-AccFix Thinline Anterior Cervical Plate System (K013979), L&K Biomed LnK Anterior Cervical Plate System (K143279), Orthofix CETRA Anterior Cervical Plate System (K162638), Globus Medical PROVIDENCE Anterior Cervical Plate System (K070775), Synthes CSLP System (K945700, K000536, K000742, K030866) and Signature Orthopaedic NOOSA Anterior Lumbar Plate System (K163625). Non-clinical testing results support the substantial equivalence claim.

Comparison of technological characteristics

Temporary immobilisation and stabilisation of spinal segments as supplemental fixation in spinal fusion procedure is the technological principle for both the subject device and the predicate devices. The subject and predicate devices are based on the following same technological elements:

- The indication for use of the subject device is the same as the predicate devices

- The intended surgery sites of the subject device is the same as intended surgery sites of the predicates
- The subject device is manufactured from the same material as the predicate devices
- The locking mechanism of the subject device is equivalent to the locking mechanism of LnK and CETRA plate systems
- The profile thickness of the subject device are within the profile thickness of the predicates
- The size range of the subject devices fall within the size range of the predicates
- The subject device accommodate the same number of supplemental as the predicate devices
- Both subject device and predicates are contoured to match the vertebral body
- Both subject device and predicates are implanted manually and the screws are hand tightened

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

- Some of the design features are different between the subject and predicate devices
- The material used on one of the predicates are slightly different than the subject device
- The material used for two of the predicate devices are slightly different than the subject device (Ti6Al4V ELI vs Ti6Al4V)
- The screw locking mechanism on two of the predicates are different the subject device

Conclusions:
Technical comparison of the subject and predicate devices demonstrates equivalence in device design, intended use, indications for use and material. Non-clinical data raises no new safety or effectiveness questions of the Pinehurst Anterior Cervical Plate System.