



Food and Drug Administration
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Synthes USA, LLC
% Ms. Laura Bleyendaal
Regulatory Affairs Associate
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325 Paramount Drive
Raynham, Massachusetts 02767

December 2, 2015

Re: K152239

Trade/Device Name: Zero-P Natural Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 6, 2015
Received: November 9, 2015

Dear Ms. Bleyendaal:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152239

Device Name

Zero-P Natural Plate System

Indications for Use (Describe)

The Zero-P Natural Plate is intended for anterior plate and screw fixation of the cervical spine. The plate and four screw system has been designed designed for use with structural allograft to provide stabilization as an adjunct to cervical fusion. Indications for use of this plate system include degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion. The plate is intended for one level in the cervical spine, from C2 to T1.

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

A. Submitter Information

510(k) Sponsor: Synthes USA, LLC
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B. Date Prepared November 6, 2015

C. Device Name

Trade/Proprietary Name: Zero-P Natural Plate System
Common/Usual Name: Spinal intervertebral body fixation orthosis
Device Classification and Regulation: Class II per 21 CFR § 888.3060
Classification Product and Panel Code: KWQ; Orthopedic

D. Predicate Device Name

Primary Predicate Device: Optio-C™ Anterior Cervical Plate System (K141500)
Additional Predicate Device: VECTRA-ONE™ Cervical Plate (K071667)

E. Device Description

The Zero-P Natural Plate is intended for anterior plate and screw fixation of the cervical spine. The Zero-P Natural Plate and four screw system has been designed to provide stabilization as an adjunct to cervical fusion. The Zero-P Natural Plate is secured to the

spine through unicortical fixation with bone screws. The plate is positioned flush with the adjacent vertebral bodies. Four bone screws attach to the plate for fixation through the adjacent vertebral bodies; two screws are directed into the superior and inferior vertebrae through the endplates.

The Zero-P Natural Plate has been designed for use with a Musculoskeletal Transplant Foundation (MTF) allograft spacer. Size pairings of the Zero-P Natural Plate and the allograft spacer are identified in the labeling to ensure a proper fit and height relationship of the allograft spacer to the Zero-P Natural Plate.

F. Indications for Use

The Zero-P Natural Plate is intended for anterior plate and screw fixation of the cervical spine. The plate and four screw system has been designed for use with structural allograft to provide stabilization as an adjunct to cervical fusion. Indications for use of this plate system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion. The plate is intended for one level in the cervical spine, from C2 to T1.

G. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The technological characteristics including material, design and performance of the Zero-P Natural Plate are consistent with those of the predicate devices.

H. Materials

The Zero-P Natural Plate and screws are manufactured from titanium alloy conforming to ASTM F1295 which is anodized.

I. Performance Data

In order to characterize the Zero-P Natural Plate and establish its substantial equivalence, mechanical, as well as biomechanical testing was conducted in a comparative manner. The mechanical properties of the Zero-P Natural Plate were evaluated through the following tests in accordance with ASTM F1717-14 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model:

- static compression bending,
- static torsion and
- dynamic compression bending.

The biomechanical properties of the Zero-P Natural Plate were evaluated through a cyclic cadaveric range of motion study in which the Zero-P Natural Plate and predicate plate were tested.

J. Conclusion

The indications for use and intended use of the Zero-P Natural Plate are consistent with that of the predicate devices. The technological characteristics of the Zero-P Natural Plate in terms of design, materials and performance are consistent with those of the predicate devices. The Zero-P Natural Plate is substantially equivalent to the aforementioned predicate devices.