



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Osseus Fusion Systems, LLC
% Mr. J.D. Webb
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

April 26, 2016

Re: K160522

Trade/Device Name: White Pearl Preferred Angle Anterior Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 12, 2016
Received: April 14, 2016

Dear Mr. Webb:

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" (21CFR 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)

K160522

Device Name

White Pearl Preferred Angle Anterior Cervical Plate

Indications for Use (Describe)

The White Pearl Preferred Angle Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion 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. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudarthrosis,
- 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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510(k) Summary: White Pearl Preferred Angle Anterior Cervical Plate

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	February 15, 2016
Submitted By	Osseus Fusion Systems, LLC 2703 Mockingbird Lane, Suite 102 Dallas, TX 75235 214-395-0100 Tele email: rpace@osseus.com
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
Trade Name	White Pearl Preferred Angle Anterior Cervical Plate
Common Name	anterior cervical plate
Classification Name	Spinal intervertebral body fixation orthosis
Class	II
Product Code	KWQ
CFR Section	21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate Device	Zimmer Trinica/Trinica Select Anterior Cervical Plate System (K132012)
Additional Predicate Devices	Spinal USA Simplicity Anterior Cervical Plate System (K060025) Synthes Anterior CSLP System (K000536) DePuy UNIPLATE Anterior Cervical Plate (K042544 / K082273 / K100070) Zimmer Optio-C Anterior Cervical System (K132894)
Device Description	The White Pearl Preferred Angle Anterior Cervical Plate consist of cervical plates, locking caps, bone screws, and the instruments necessary to implant this specific system. All implant components are made from a titanium alloy (Ti-6Al-4V ELI). The White Pearl Preferred Angle Anterior Cervical Plate is intended to provide stabilization of the cervical vertebrae for various indications. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and/or self-drilling bone screws using an anterior approach. Bone screws are available for fixed angle or variable angle implantation. The White Pearl Preferred Angle Anterior Cervical Plate is intended to be removed after solid fusion has occurred.
Materials	Titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136

Substantial Equivalence Claimed to Predicate Devices	The White Pearl Preferred Angle Anterior Cervical Plate is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	<p>The White Pearl Preferred Angle Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:</p> <ul style="list-style-type: none"> • 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. fractures or dislocations), • tumors, • deformity (defined as kyphosis, lordosis, or scoliosis), • pseudarthrosis, • failed previous fusion, • spinal stenosis
Non-clinical Test Summary	<p>The following analyses were conducted:</p> <ul style="list-style-type: none"> • Static and dynamic compression testing per ASTM F1717 • Static torsion testing per ASTM F1717 <p>The results of these evaluations indicate that the White Pearl Preferred Angle Anterior Cervical Plate is substantially equivalent to the predicate devices.</p>
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	The White Pearl Preferred Angle Anterior Cervical Plate is substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.