



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2016

Osteomed Implantes, LTDA
% Mr. J.D. Webb
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K151553

Trade/Device Name: 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: January 5, 2016
Received: January 8, 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 Parts 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,

Lori A. Wiggins -S

for
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)
K151553

Device Name
Anterior Cervical Plate System

Indications for Use (Describe)

The Anterior Cervical Plate System 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: Anterior Cervical Plate System

Date Prepared	June 5, 2015
Submitted By	Osteomed Implantas, LTDA Washington Luiz Road, km 172 Condomínio Conpark – Rua 6, S/N CEP 13501-600 Rio Claro - SP BRAZIL (19) 3532-3411 Tele
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele 512-692-3699 Fax e-mail: jdwebb@orthomedix.net
Trade Name	Anterior Cervical Plate System
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	Cervical Spine Locking Plate (CSLP) - Synthes (K031276/K030866/K000742/ K000536/K945700)
Additional Predicate Devices	C-Tek MaxAn Anterior Cervical Plate System - Biomet Spine (K080646) UNIPLATE ANTERIOR CERVICAL PLATE, - DePuy (K042544 / K082273 / K100070)
Device Description	The Osteomed Implantas Anterior Cervical Plate System is intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping bone screws using an anterior approach. Plates are available in a variety of lengths (22 mm - 110mm), addressing multiple levels of fixation (one to six). The Osteomed plate incorporates holes or vision ports on the longitudinal center line for intraoperative visualization and for screw fixation of bone graft. Bone screws are available in two diameters (Ø3.85 mm and Ø4.25 mm) and a variety of lengths (8mm – 20mm).
Materials	Commercially pure titanium conforming to ASTM F67 Titanium alloy (Ti6Al4V) conforming to ASTM F136
Substantial Equivalence Claimed to Predicate Devices	The Anterior Cervical Plate System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety, and performances.

Indications for Use	<p>The Anterior Cervical Plate System 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 per ASTM F1717 • Static torsion per ASTM F1717 <p>The results of these evaluations indicate that the Anterior Cervical Plate System is equivalent to predicate devices.</p>
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Osteomed Implantes considers the Anterior Cervical Plate System to be equivalent to the predicate device listed above. This conclusion is based upon the device's similarities in principles of operation, technology, materials, and indications for use