JUN 09 2014

510(k) Summary

Prepared 06/03/2014

Name and Address of Manufacturer

The Orthopaedic Implant Company (OIC)
316 California Ave #701
Reno, NV 89509

Contact

Douglas Fulton
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Device Identification

Trade Name: OIC Variable Angle Small Fragment Locking Plate System
Common Name: Plate, fixation, bone Screw, fixation, bone
Classification Name: Single/Multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Classification: Class II, 21 CFR 888.3030, 888.3040
Panel: Orthopedic
Product Code: HRS, HWC

Indications for Use

The OIC Variable Angle Small Fragment Locking Plate System is indicated for the fixation of fractures, mal-unions, non-unions or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, tibia, fibula, malleolus and metatarsal.

Device Description

The OIC Variable Angle Small Fragment Locking Plate System consists of titanium plates for the Distal Radius, Clavicle, Proximal Humerus, Tibia and Distal Fibula, bone screws and instruments for implantation. The plates come in a variety of sizes and are pre-contoured to match the anatomy of the patient and accept 2.5mm and 3.5mm bone screws. The bone screws are available in two diameters (2.5mm and 3.5mm) and range in length from 6mm to 130mm. The bone screws are available with both threaded (locking) and non-threaded (non-locking) heads.

The OIC Variable Angle Small Fragment Locking Plate System implants are made of titanium alloy or cp titanium in compliance with ASTM F136 or ASTM F67.

The devices conform to the following standards:

ASTM F543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws
ASTM F382, Standard Specification and Test Method for Metallic Bone Plates

The OIC Variable Angle Small Fragment Locking Plate System is provided non-sterile and is steam-sterilized by the medical facility prior to implantation.

Substantial Equivalence

Predicate devices:
K001170 Synthes 2.7mm LC-DCP, 3.5mm Profile (Limited Contact – Dynamic Compression Plate)
K033669 Smith & Nephew Locking Bone Plate System
K050646 Synthes (USA) 3.5 / 4.5mm LCP Medial Proximal Tibia Plates
K051735 Peri-Loc Locking Bone Plates and Locking Bone Screws for the Upper Extremity
K061352 Peri-Loc Periarticular Locked Plating System – Locking Bone Plates & Screws for the Upper Extremity
K071184 Synthes Variable Angle – Locking Compression Plate (VA-LCP) Distal Radius System
K071563 Peri-Loc Periarticular Locked Plating System – VLP Locking Bone Plates & Screws
K071715 Acumed Congruent Bone Plate System
K080522 Synthes 3.5mm LCP Distal Tibia T Plates
K083032 PERI-LOC Bone Plating and Screw System
K123832 OIC Distal Radius Plating System, OIC Proximal Humerus Plating System, OIC Clavicle Plating System

The new device is substantially equivalent to the predicate devices in regards to intended use, materials, and function. There are no significant differences between the OIC Variable Angle Small Fragment Locking Plate System and the predicate devices listed above. Any minor differences have no effect on safety and effectiveness.

The screws, the plates, the locking interfaces and the behavior of the OIC Variable Angle Small Fragment Locking Plate System were evaluated using finite element stress/strain analyses (FEA). The screws, the plates and the plate-screw constructs were found to have acceptable mechanical characteristics for the intended uses. Similarly, each screw design, plate design and each locked screw-plate sub-construct and repair construct was found to have similar mechanical performance compared to similar devices used for the same indications as identified via a literature review.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 9, 2014

The Orthopaedic Implant Company
Mr. Douglas Fulton
Quality Assurance Manager
316 California Avenue, Suite 701
Reno, Nevada 89509

Re: K140357
Trade/Device Name: OIC Variable Angle Small Fragment Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 19, 2014
Received: May 21, 2014

Dear Mr. Fulton:

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,

Lori A. Wiggins

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140357

Device Name
OIC Variable Angle Small Fragment Locking Plate System

Indications for Use *(Describe)*

The OIC Variable Angle Small Fragment Locking Plate System is indicated for the fixation of fractures, mal-unions, non-unions or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, tibia, fibula, malleolus and metatarsal.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth D Frank -S

Division of Orthopedic Devices