JAN 17 2014

510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Bone Fragment Fixation Plates and Screws device is provided below.

Device Common Name: Plate, Fixation, Bone Screw, Fixation, Bone Washer

Device Proprietary Name: Bone Fragment Fixation Plates, Screws and Washers

Submitter: Laura Cattabriga
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N. Bay Village, Florida 33141

Contact: Laura Cattabriga
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N. Bay Village, Florida 33141
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Classification Regulation: 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener (HWC)

21 CFR 888.3030: Single / multiple component metallic bone fixation appliances and accessories (HRS, HTN)

Panel: Orthopedics

Product Code: **HWC, HRS, HTN**

Indication for Use: The Core Orthopaedics bones plates and screws system are intended to be used for internal fixation of bone fractures, fusions or osteotomies in the ankle, foot, hand, wrist, clavicle, scapula, pelvis, long bone (such as humerus, ulna, radius, femur, tibia, and fibula, and small bones (such as metacarpals, metatarsals, phalanges). The washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of large bone and bone fragments.

Device Description: The bone fragment fixation plates and washers of various sizes, consists of various shapes as well as screws are intended to treat fractures and osteotomies of various bones, including the clavicle, acetabulum, pelvis, scapula, humerus, radius, ulna, femur, tibia, phalanges, carpals, metacarpals, tarsals, metatarsals and fibula. The washers are to function with

screws to prevent the screw head from breaking through the cortex of the bone by providing additional surface area during screw placement. The plates, screws, and washers are a one-piece device made of stainless steel.

Performance Data: The Bone Fragment Fixation Plates Screws and Washers are substantially equivalent to the predicate devices with respect to design and material and dimensional comparison.

Substantial Equivalence:

- Internal Fixation Systems, Inc. Bone Plates Screws and Washers (K110086)
- Synthes Spherical Washers (K052483)

Technological Characteristics Comparison: The Bone Fragments Fixations Plates and Screws are equivalent to the predicate devices with respect to design, material and dimensional comparison.

Sterilization Information: The Bone Fragment Fixations Plates and Screws will be distribute non-sterile. The devices are sterilized by the end user per the AAMI Guidelines "Good Hospital Practice: Steam Sterilization and Sterility Assurance" and ANSI/AAMI/ISO 11737 guidelines to achieve the Sterility Assurance Level (SAL) of 10-6.

Conclusion: There are no significant differences between the Bone Fragment Fixations Plates and Screws and the other implants as listed in the Substantially Equivalence Devices. The Bone Fragment Fixations Plates and Screws and the predicate devices have similar design attributes, materials, and intended use thus is substantially equivalent.

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

January 17, 2014

Laura H. Cattabriga
Chief Operating Officer / Chief Financial Officer
7430 Center Bay Drive
Miami, Florida 33143

Re: K130614
Trade/Device Name: Bone Fragment Fixation Plates and Screws
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, HTN
Dated: December 17, 2013
Received: December 18, 2013

Dear Ms. Cattabriga:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 Statement

510(k) Number (if known): K130614

Device Name: Bone Fragment Fixation Plates and Screws

Indications For Use:

The Core Orthopaedics bones plates and screws system are intended to be used for internal fixation of bone fractures, fusions or osteotomies in the ankle, foot, hand, wrist, clavicle, scapula, pelvis, long bone (such as humerus, ulna, radius, femur, tibia, and fibula, and small bones (such as metacarpals, metatarsals, phalanges). The washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of large bone and bone fragments.

Prescription Use __ X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices