JAN - 6 2014

ACUMED®

Acumed Hand Plating System - 510(k) Notification

Section 6: 510(k) Summary

Device Trade Name: Acumed Hand Plating System

Common Name: Hand Plating System

Classification: 21 CFR 888. 3030, (Single/multiple component metallic bone fixation appliances and accessories)

Manufacturer: Acumed, LLC
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

Contact: Ms. Mariah Knight
Regulatory Specialist
Phone: 503-207-1530
Fax: 503-520-9618

Date Prepared: August 30, 2013

Class: II

Product Code: HRS, HWC

Device Description: The Hand Plating System consists of plates, locking screws, lag screws, and k-wires.

Plates are available in a variety of shapes to accommodate varying fracture patterns and/or patient anatomy. The plates come in thicknesses of 0.8 mm to 1.3 mm. The locking screws and lag screws have major thread diameters of 1.5 mm to 2.3 mm, provided in lengths ranging from 5 mm to 20 mm. The lag screws and k-wires are used for fixation independent of the plates.

The plates are made of titanium per ASTM F-67. The screws, lag screws, and the k-wires are made of titanium alloy per ASTM F136.

All plates and screws are provided sterile and non-sterile.

Intended Use: The Acumed Hand Plating System is intended for the management of fractures, fusions, and osteotomies of the distal, middle, and proximal phalanges and metacarpals and other bones of appropriate size for the devices.

Legally Marketed Predicate Device(s): The Hand Plating System has the following predicate devices:

Device:	Profyle System
510(k):	K062498
Applicant:	Howmedica Osteonics Corp
Product Code:	HRS

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Device:	APTUS Titanium Fixation System
510(k):	K051567
Applicant:	Medartis, Inc.
Product Code:	HRS

Device:	APTUS 1.5 TriLock
510(k):	K102537
Applicant:	Medartis AG
Product Code:	HRS

Device:	OsteoMed Hand Plate and Screw Fixation System
510(k):	K090522
Applicant:	OsteoMed L.P.
Product Code:	HRS, HWC

Substantial Equivalence:

The Acumed Hand Plating System is substantially equivalent to the previously cleared Howmedica Profyle System (K062498), Medartis APTUS Titanium Fixation System (K051567), Medartis APTUS 1.5 Trilock (K102537), and OsteoMed Hand Plate and Screw Fixation System (K090522). The safety and effectiveness is adequately supported by the substantial equivalence information, materials information, and analysis provided within this Premarket Notification.

The proposed Acumed Hand Plating System and the predicate devices consist of similar design features, operating principles, material of composition, and intended use.

Non-Clinical Testing:

The non-clinical testing enclosed in this submission includes static and cyclic performance testing and engineering analysis.

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 6, 2014

Acumed, LLC
Ms. Mariah Knight
Regulatory Specialist
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K132769
Trade/Device Name: Hand Plating 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: November 26, 2013
Received: December 2, 2013

Dear Ms. Knight:

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,

Ronald P. Jean -S for

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

Enclosure

K132769

Indications for Use

Device Name: Hand Plating System
Indications for Use:

The Acumed Hand Plating System is intended for the management of fractures, fusions, and osteotomies of the distal, middle, and proximal phalanges and metacarpals and other bones of appropriate size for the devices.

Prescription Use ___√___ 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