JUN 13 2014

Section 7 – 510(k) Summary

510(k) Summary

Contact Details

Applicant Name: Acumed LLC
5885 NW Cornelius Pass Road, Hillsboro, OR 97124-9432

Mariah Knight, Regulatory Specialist
503-207-1530

Date Prepared: May 22, 2014

Device Name

Trade Name: Acumed Hand Fracture System

Common Name: Hand Plating System

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

Class: II

Product Code: HRS, HWC

Legally Marketed Predicate Device(s)

The *Acumed Hand Plating System* cleared in *2013* (K132769*)* serves as the predicate device.

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 have major thread diameters of 1.5 mm to 2.3 mm and are provided in

lengths ranging from 5 mm to 20 mm. The lag screws have major thread diameters of 1.5 mm to 2.3 mm, provided in lengths ranging from 8 mm to 18 mm.The lag screws and k-wires are used for fixation.

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.

Intended Use/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.

Substantial Equivalence Comparison

The Acumed Hand Plating System is substantially equivalent to the predicate K132769. 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 same technological characteristics, design features, materials of composition, and intended use.

The proposed Acumed Hand Plating System possesses a modified operating priniciple in that the lag screws may be used with the plates, in addition to being used independently for fixation.

Non-clinical Testing

Engineering analysis was conducted that proved that the 1.5 and 2.3 mm Hexalobe Lag Screws can be used with the Acumed Hand Plates.

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 13, 2014

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

Re: K141383
Trade/Device Name: Acumed Hand Fracture 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 22, 2014
Received: May 27, 2014

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 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 below.

510(k) Number *(if known)*
K141383

Device Name
Acumed Hand Fracture System

Indications for Use *(Describe)*
The Acumed Hand Fracture 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

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

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.

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