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

April 6, 2015

Acumed, LLC
Mr. Nathan Wolf
Regulatory Specialist
5885 North West Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K143385
Trade/Device Name: Acumed Ankle 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: March 4, 2015
Received: March 6, 2015

Dear Mr. Wolf:

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,

Mark N. Melkerson -S

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)*

K143385

Device Name
Acumed Ankle Plating System

Indications for Use *(Describe)*

The Acumed Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula, particularly in osteopenic bone.

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.

510(k) Summary

Contact Details

Applicant Name: Acumed LLC
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Date Prepared: 24 November 2014

Device Name

Trade Name: Acumed Ankle Plating System

Common Name: Ankle Plating System

Classification: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

Class: Class II

Product Code: HRS, HWC

Legally Marketed Predicate Device(s)

The Synthes Third Tubular Plate (pre-amendment per K011335), Synthes VA LCP Ankle Trauma System cleared in 2012 (K120854), and the Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates cleared in 2008 (K083213) serve as the predicate devices.

Device Description

The Acumed Ankle Plating System consists of plates and accompanying screws implanted in the distal fibula and tibia. The plates are available in a variety of sizes and use a variety of screw sizes to accommodate varying patient anatomies and fracture patterns. All plates are anatomically pre-contoured, and are provided in left and right limb-specific options where applicable. All implants are manufactured from Ti-6Al-4V per ASTM F136 and provided both sterile and non-sterile. The system contains pre-contoured plates, 2.7, 3.5, and 4.0mm screws, syndesmosis targeting instrumentation, and other typical instrumentation for ankle plating cases.

Intended Use/Indications for Use

The Acumed Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula, particularly in osteopenic bone.

Substantial Equivalence Comparison

In consideration of the comparisons given herein, the Acumed Ankle Plating System has been determined to be substantially equivalent to its predicate devices, the Synthes Third Tubular Plates (pre-amendment), Synthes VA LCP Ankle Trauma System (K120854), and Synthes 2.7 mm/3.5 mm LCP Distal Fibula Plates (K083213). Substantial equivalence was determined due to similarities in materials, technology, function, and dimensions.

Non-clinical Testing

Comparative testing between the Acumed Ankle Plating System and a predicate device was conducted per ASTM F382-99. The test data showed the Acumed Ankle Plating System was substantially equivalent to the predicate device in both static four-point bend and bending fatigue tests as described herein.