



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Acumed, LCC
% Mr. Nathan Wolf
Regulatory Consultant
Wolf Regulatory Consulting LLC
P.O. Box 796
Loma Linda, California 92354

October 30, 2015

Re: K151886
Trade/Device Name: Acumed Ankle and Small Fragment Base Set Update
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: September 28, 2015
Received: October 1, 2015

Dear Mr. Nathan 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" (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 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 AdministrationForm Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.**Indications for Use**

510(k) Number (if known)

K151886

Device Name

Acumed Ankle and Small Fragment Base Set Update

Indications for Use (Describe)

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

The Acumed Small Fragment Base Set contains orthopedic plates and screws with the following indications: Acumed Hook Plates and Locking Peg Hook Plates are intended for fixation of fractures, osteotomies, and non-unions of small bones including the ulna, radius, tibia, and fibula. Acumed Fragment Plates and 4.0mm Cancellous Screws are intended for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments. Acumed One-Third Tubular Plates are intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Acumed Ankle and Small Fragment Base Set Update
510(k) Notification

510(k) Summary

Contact Details

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

Applicant Contact: Ms. Kara Budor, Regulatory Manager
503-207-1413
503-520-9618 (Fax)

Correspondent: Mr. Nathan Wolf, Regulatory Consultant
858-263-0605
nathan@wolfregulatory.com

Date Prepared: July 7, 2015

Device Name

Trade Name: Acumed Ankle and Small Fragment Base Set Update

Common Name: Bone Plates and Bone Screws

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 Acumed Ankle Plating System cleared in 2015 (K143385), Acumed Small Fragment Base Set cleared in 2015 (K143394), Howmedica Osteonics Stryker® Foot Plating System cleared in 2007 (K063875), Howmedica Osteonics VariAx™ Distal Fibula Plate cleared in 2008 (K081284), and Smith & Nephew Peri-Loc™ Periarticular Locked Plating System cleared in 2007 (K071563) serve as the predicate devices for this system.

Device Description

The Acumed Ankle and Small Fragment Base Set Update introduces new 2.7mm and 3.5mm variable angle screws for use with previously cleared plates from the Acumed Ankle Plating System (K143385) and Acumed Small Fragment Base Set (K143394).

Additionally, this submission expands the Ankle Plating System to include use of existing 2.7mm and 3.5mm non-locking screws in independent bone fixation, for the K143385 indications.

Intended Use/Indications for Use

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

The Acumed Small Fragment Base Set contains orthopedic plates and screws with the following indications: Acumed Hook Plates and Locking Peg Hook Plates are intended for fixation of fractures, osteotomies, and non-unions of small bones including the ulna, radius, tibia, and fibula. Acumed Fragment Plates and 4.0mm Cancellous Screws are intended for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments. Acumed One-Third Tubular Plates are intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula.

Substantial Equivalence Comparison

In consideration of the comparisons given herein, the Acumed Ankle and Small Fragment Base Set Update has been determined to be substantially equivalent to its predicate devices. Substantial equivalence was determined due to similarities in materials, technology, function, and dimensions.

Non-clinical Testing

Non-clinical included:

- ASTM F543 comparative testing
- Cantilever bend comparative testing
- Galvanic corrosion analysis

Test data showed the variable angle screws introduced in this 510(k) submission are substantially equivalent to predicate devices.