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 23, 2015

Acumed, LCC
Nathan Wolf
Regulatory Specialist
5885 NW Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K143394
Trade/Device Name: Acumed Small Fragment Base Set
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: December 9, 2014
Received: December 12, 2014

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" (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)*
K143394

Device Name
Acumed Small Fragment Base Set

Indications for Use *(Describe)*
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.

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510(k) Summary

Contact Details

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

Nathan Wolf, Regulatory Specialist
503-726-6622 (Cell)
503-207-1502 (Desk)
503-520-9618 (Fax)

Date Prepared: 05 January 2015

Device Name

Trade Name: Acumed Small Fragment System

Common Name: Bone Plates and 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 Synthes (USA) Modular Mini Fragment LCP System cleared in 2006 (K063049), Synthes (USA) 3.5mm LCP Hook Plate cleared in 2008 (K082072), Synthes One-Third Tubular DCL Plate cleared in 2001 (K011335), and Synthes Sterile 3.5mm and 4.0mm Cannulated Screws cleared in 1996 (K963192) serve as predicate devices.

Device Description

The Acumed Small Fragment Base Set contains orthopedic plates and screws indicated for general fragment fixation as described below. Plates and screws are manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F136, or from commercially pure titanium per ASTM F67. All implants are provided both sterile and non-sterile. The set also contains typical instrumentation for general orthopedic fracture fixation cases.

Intended Use/Indications for Use

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 Small Fragment Base Set has been determined to be substantially equivalent to its predicate devices, the Synthes (USA) Modular Mini Fragment LCP System (K063049), Synthes (USA) 3.5mm LCP Hook Plate (K082072), Synthes One-Third Tubular DCL Plate (K011335), and Synthes Sterile 3.5mm and 4.0mm Cannulated Screws (K963192). Substantial equivalence was determined due to similarities in materials, technology, function, and dimensions.

Non-clinical Testing

Comparative testing between the Acumed Small Fragment Base Set implants and similar devices was conducted as follows:

- Fragment Plate static bending strength and cyclic fatigue testing was performed per ASTM F382.
- One-Third Tubular Plate static bending strength and cyclic fatigue testing was performed per ASTM F382.
- Hook Plate static bending strength and cyclic fatigue testing was performed per ASTM F384
- Locking Peg Hook Plate static bending strength and cyclic fatigue testing was performed per ASTM F384
- 4.0 Cancellous Screw pullout and torque testing was performed per ASTM F543.

The results provided in Section 20 demonstrate the substantial equivalence of the Acumed Small Fragment Base Set.