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K100123

OCT 6 2010

510(k) Summary

Contact:	Lino Tsai Acumed, LLC 5885 NW Cornelius Pass Rd. Hillsboro, OR 97124-9432 (503) 627-9957 x 1370 FAX: (503) 686-7102
Device Trade Name:	Acumed Wrist Arthrodesis Plate System
Manufacturer:	Acumed, LLC 5885 NW Cornelius Pass Rd. Hillsboro, OR 97124-9432
Common Name:	Plate, Fixation, Bone
Classification:	21 CFR 888.3030
Class:	II
Product Code:	HRS
Date:	September 24, 2010

Indications for Use:
The Acumed Wrist Arthrodesis Plate System is intended for wrist arthrodesis and fractures of other small bones. Specific indications include post-traumatic arthritis of the joints of the wrist, rheumatoid wrist deformities requiring restoration, complex carpal instability, post-septic arthritis of the wrist, severe unremitting wrist pain related to motion, brachial plexus nerve palsies, tumor resection, and spastic deformities.

Device Description:
The Acumed Wrist Arthrodesis Plates are pre-contoured with an anatomic design with multiple wrist extension positions. The plates have a combination of distal and proximal holes which utilize 2.3 mm and 3.5 mm cortical locking and non-locking screws.

Technological Characteristics:

The plates and screws are made of titanium alloy, Ti 6Al 4V, per ASTM F136. The plates are supplied in multiple wrist positions. The predicate devices share these dimensional and material characteristics. There are no technological characteristics that raise new issues of safety or effectiveness.

An engineering analysis of plate strength was conducted to compare the Acumed Wrist Arthrodesis Plate to the predicate device. Calculations based on cross-sect6ional area and plate material showed that the Acumed Wrist Arthrodesis Plate is able to withstand more load than the predicate device before plastic deformation.

Mechanical testing of distal screw pull-out strength was conducted comparing the Acumed Wrist Arthrodesis Plate to the predicate device. The results showed that the Acumed Wrist Arthrodesis Plate required equivalent force and significantly more energy to cause distal screw pull-out than the predicate device.

Predicate Device(s):

Synthes LCP Wrist Fusion Plate - K042355
Synthes Small Titanium Wrist Fusion Plate - K023879
Synthes Straight Wrist Fusion Plate - K011458
Synthes Wrist Fusion Plate - K000558
DVO Wrist Fusion Plate - K052754
KMI Wrist Fusion System - K991873

Based upon the similarities of the Acumed Wrist Arthrodesis Plate System and the predicate devices studied, the safety and effectiveness of the Acumed Wrist Arthrodesis Plate System is substantially equivalent to the predicate devices referenced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Acumed LLC
% Ms. Lino Tsai
Regulatory Specialist
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124-9432

OCT 6 2010

Re: K100123
Trade/Device Name: Acumed Wrist Arthrodesis Plate 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
Dated: August 26, 2010
Received: August 27, 2010

Dear Ms. Tsai:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

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

Enclosure

ACUMED®
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Indications for Use

510(k) Number (if known): K100123

Device Name: Acumed Wrist Arthrodesis Plate System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janette Jones for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100123