K131380

JUN 1 0 2013

Section 4: 510(k) SUMMARY

Device Trade Name:	Acumed Wrist Arthrodesis Plate System: Acumed Total Wrist Fusion Plating System
Date:	May 10, 2013
Sponsor:	Acumed, LLC 5885 NW Cornelius Pass Road Hillsboro, OR 97124 Phone: (503) 627-9957 Fax: (503) 520-9618
Contact Person:	Brittany Cunningham, Regulatory Specialist 2
Manufacturer:	Acumed, LLC 5885 NW Cornelius Pass Road Hillsboro, OR 97124 Phone: (503) 207-1467 Fax: (503) 520-9618
Common Name:	Plate, Fixation, Bone
Device Classification:	Class II
Classification Name:	Plate, Fixation, Bone
Regulation:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Device Regulation Panel:	Orthopedic
Device Product Code:	HRS, HWC

Device Description:
The Acumed Total Wrist Fusion Plating System contains plates which are pre-contoured with an anatomic design. The plates have a combination of distal and proximal holes which utilize 2.3 mm and 3.5 mm cortical locking screws and non-locking screws. The purpose of the Special 510(k) submission is to gain marketing clearance for modifications to the previously cleared Acumed Wrist Arthrodesis Plate System including modifications to existing plates, the addition of the Neutral plate and the modified 2.3 mm screw.

Intended Use:
Wrist arthrodesis and fractures of other small bones

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.

Materials:
The Acumed Total Wrist Fusion Plating System components are manufactured from titanium alloy (Ti-6Al-4V) as described in ASTM F136.

Technological Characteristics:
The plates and screws are made of titanium alloy (Ti-6AI-4V) per ASTM F136. The predicate devices share these dimensional and material characteristics. There are no technological characteristics that raise new issues of safety or effectiveness.

Performance Data:
Engineering rationales including calculations of moments of inertia and cross-sectional area were conducted to prove that the subject plates and screws are substantially equivalent to the predicate plates and screws.

Distal screw construct pull-out bench testing was also performed to prove that the distal subject screw-plate construct is substantially equivalent to the distal predicate screw-plate construct.

A discussion of clinical tests is not applicable.

Predicate Device: (modified to subject device)
Acumed Wrist Arthrodesis Plate System – K100123

Previous Predicates: (For modified device)
Synthes LCP Wrist Fusion Plate – K042355
Synthes Small Titanium Wrist Fusion Plate – K023870
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 Total Wrist Fusion Plating Device and the predicate devices studied, the safety and effectiveness of the Acumed Total Wrist Fusion Plating System is substantially equivalent to the predicate devices referenced.

The term "substantial equivalence" as used in this Special 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and applied under 21 CFR 807, Subpart E, under which a device can be marketed without the pre-approval or classification.

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 10, 2013

Acumed, LLC
% Ms. Brittany Cunningham
Regulatory Specialist II
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K131380
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, HWC
Dated: May 10, 2013
Received: May 14, 2013

Dear Ms. Cunningham:

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 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. 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 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,

For Erin D. Keith

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: INDICATIONS FOR USE

510(k) Number (if known): K131380

Device Name: Acumed Wrist Arthrodesis Plate System

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.

Prescription Use X AND/OR Over-the-Counter Use

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Elizabeth L. Frank -S

Division of Orthopedic Devices