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ACUMED®, LLC

AUG - 9 2007

5885 N.W. Cornelius Pass Road, Hillsboro, Oregon 97124-9432 Tel (503) 627-9957

510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information: Acumed LLC
5885 N.W. Cornelius Pass Road
Hillsboro, OR 97124-9432
USA
Phone: (503) 627-9957
FAX: (503) 686-7102
Contact: Ed Boehmer, Regulatory Compliance Officer

Classification Name:	Rod, Fixation, Intramedullary and Accessories
Common Name:	Radius, Ulna, and Fibula Rods
Proprietary Name:	Acumed Small Bone Locking Rod System II
Proposed Regulatory Class:	Class II, 21 CFR 888.3020
Device Product Code:	HSB
Legally Marketed Equivalent Device(s):	Acumed Small Bone Locking Rod System II K031438

Device Description: The Acumed Small Bone Locking Rod II is an intramedullary rod with solid and cannulated versions. Rods are manufactured in multiple lengths (110 mm to 270mm) and diameters (3.0 to 4.5 mm). The rod has openings used in conjunction with cortical screws, which lock it in place.

Intended Use: The Acumed Small Bone Locking Rod II System is indicated for use in fractures and osteotomies of the fibula, radius, and ulna. These are similar to intended use of predicate devices and do not raise new issues of safety and effectiveness.

Technological Characteristics: The Acumed Small Bone Locking Rods II are slightly bowed rods made from titanium alloy in conformance with ASTM F136 and stainless steel ASTM F138 and ASTM F2229. Both titanium alloy and stainless steel have been successfully used in numerous intramedullary rods. There are no technological characteristics that raise new issues of safety or effectiveness.

An assessment of performance data is not applicable.
A discussion of clinical and non-clinical tests is not applicable.

Based upon the similarities of the Acumed Small Bone Rod II System and the predicate devices studied, the safety and effectiveness of the Acumed Small Bone Rod II System is substantially equivalent to the predicate devices referenced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Acumed, LLC
% Mr. Ed Boehmer
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

AUG - 9 2007

Re: K071944
Trade/Device Name: Acumed Small Bone Locking Rod System II
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: July 11, 2007
Received: July 13, 2007

Dear Mr. Boehmer:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications For Use

510(k) Number (if known): K071944

Device Name: Acumed Small Bone Locking Rod System II

Indications For Use:

The Acumed Small Bone Locking Rod System II includes rods and screws, with accessories, for indicated use for fractures and osteotomies of the radius, ulna, and fibula.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (Part 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 (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071944