JUL 17 2002

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

K021321

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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, Inc.
5885 NW Cornelius Pass Road
Hillsboro, Oregon 97007 U.S.A.
Phone: (503) 627-9957
Contact: Carrie McMichael, Regulatory Affairs

Classification Name: Single/multiple component metallic bone fixation and accessories

Common Name: Plate, Fixation, Bone

Proprietary Name: Wrist Fusion Plate

Proposed Regulatory Class: Class II, 21 CFR 888.3030

Legally Marketed Equivalent Device(s): **KMI Wrist Fusion System (K991873)**
Acumed Congruent Bone Plate System (K012655)

Device Description: The Acumed Wrist Fusion Plate is spherical in shape. Holes or slots offer multiple screw placement options. The plate also has holes that may be utilized for provisional tacking or positioning with Kirschner wires to the bones prior to screw installation. A threaded hole in the center of the plate allows for optional accessories to be attached to the plate.

Intended Use: The current Acumed Congruent Bone Plate System includes plates and screws for fractures, fusions, or osteotomies designed specifically for the clavicle, humerus, radius, ulna, metatarsals, malleoulus, tibia, fibula, and metacarpals. The Acumed Wrist Fusion Plate, an addition to the Acumed Congruent Bone Plate System, is designed specifically for fusion of the small bones of the hand including: hamate, capitate, lunate, triqueteral and is for use in patients suffering pain and/or loss of function due to osteoarthritis, post-traumatic arthritis, fractures, revision of failed partial wrist fusions, carpal instability, or rheumatoid arthritis. This is similar to the KMI Wrist Fusion System intended use and does not raise any new issues of safety and effectiveness.

Technological Characteristics: The Acumed Wrist fusion Plate is a spherical, metal plate made from titanium in conformance with ASTM F136. The KMI Wrist Fusion Plate is a conical, metal plate made from 316L Stainless Steel. Both materials are used in numerous bone plates and screws. There are no technological characteristics that raise new issues of safety and effectiveness.

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

Based upon the similarities between the Acumed Wrist Fusion Plate and the predicate devices studied, the safety and effectiveness of the Acumed Wrist Fusion Plate is substantially equivalent to the predicate devices mentioned above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2002

Ms. Carrie McMichael
Regulatory Affairs Deputy
Acumed, Inc.
5885 NW Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K021321
Trade/Device Name: Wrist Fusion Plate
Regulation Number: 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: II
Product Code: HRS
Dated: April 22, 2002
Received: April 25, 2002

Dear Ms. McMichael:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021321

Device Name: Wrist Fusion Plate

Indications For Use:

The Wrist Fusion Plate and accessories are designed specifically for fusion of the small bones of the hand including: hamate, capitate, lunate, triqueteral.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K021321

(Optional Format 3-10-98)