K012655

NOV 0 7 2001

Appendix V - 510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

Classification Name: Plate, Fixation, Bone
Common Name: Bone Plate
Proprietary Name: Congruent Bone Plate System
Proposed Regulatory Class: II
Device Product Code: HRS
Manufacturing Facility: Acumed, Inc.
10950 SW 5th Street, Suite 170
Beaverton, OR 97005 U.S.A.
Establishment Registration No.: 3025141
Contact: Shari Jeffers
Labeling/Promotional Materials: See Appendix III
Substantial Equivalence:
The Acumed Congruent Bone Plate System is similar in indication, intended use, material, design, and size to Howmedica's Distal Humeral Plate (K890939) and Luhr Fixation System (K951415), to Synthes' Curved Reconstruction Plate (K011334), the Modular Foot System (K001941), and the One-Third Tubular Plate (K011335), and to Link's May Tibia Bone Plates (K912936). Literature on these predicate devices is included in Appendix IV.

The Congruent Bone Plate System consists of bone plates and screws for fractures, fusions, and osteotomies. The bone plates are pre-bent to minimize bending which is done intraoperatively. Instruments are supplied with the implants to aid in the insertion of the plates and screws. Each of the plate styles utilizes the same screw types and screw instruments for insertion. All of the plates and screws are manufactured from titanium and are provided non-sterile. The screws were cleared for marketing and distribution under K942340 and K942341.

Congruent Bone plates are provided non-sterile and are individually packaged in a plastic bag. On file at Acumed is data which shows that the instrumentation and implants can be successfully steam sterilized under specific process parameters which will obtain a resulting SAL of 10^{-6}. Information regarding labeling has been provided.

Predicate devices that are substantially equivalent to Acumed's Congruent Bone Plate System are Howmedica's Distal Humeral Plate and Luhr Fixation System; Synthes' Curved Reconstruction Plate, the Modular Foot System, and the One-Third Tubular Plate; and Link's May Tibia Bone Plates. All the devices mentioned above are manufactured from similar material, and have the same indication/intended use and similar design and size characteristics.
Based on the similarities between the Acumed Congruent Bone Plate System and the predicate devices studied, the safety and effectiveness of the Acumed Congruent Bone Plate System is expected to be similar to the predicate devices mentioned above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Ms. Shari Jeffers
Manager of Regulatory Affairs
Acumed, Inc.
10950 SW 5th Street, Suite 170
Beaverton, Oregon 97005

Re: K012655
Trade/Device Name: Acumed Congruent Bone 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 6, 2001
Received: August 13, 2001

Dear Ms. Jeffers:

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,

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

Enclosure

NOV 0 7 2001

510(k) Number (if known): K012655

Device Name: Congruent Bone Plate System

Indications For Use:

The Acumed Congruent Bone Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.

(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 K012655

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)