510(k) Summary

JAN - 4 2011

Device Trade Name: Congruent Bone Plate System

Manufacturer: Acumed, LLC
5885 NW Cornelius Pass Road
Hillsboro, OR 97124

Contact: Mr. Ed Boehmer
Global Regulatory and Quality Director
Chief Compliance Officer
Phone: (503) 627-9957

Prepared by: Musculoskeletal Clinical Regulatory Advisers, LLC
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Date Prepared: December 14, 2010

Classification: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

Class: II

Product Code: HRS

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.

Device Description:
The predicate Congruent Bone Plate System (K012655) consists of bone plates and screws which provide fixation for fractures, fusions, and osteotomies of the clavicle, humerus, radius, ulna, metacarpal, metatarsal, malleolus, tibia, and fibula.

The purpose of this 510(k) is to modify two components of the Congruent Bone Plate System and to add one component to this predicate system. These modifications are intended to allow the operating surgeon to better accommodate various patient anatomies when treating distal and midshaft fractures of the radius. All components are made of titanium alloy conforming to ASTM F136.

Predicate Device:
The modified Congruent Bone Plate System is substantially equivalent to the predicate Congruent Bone Plate System previously cleared in K012655 with respect to indications, design, function, and materials.

Preclinical Testing:
The new components were subjected to static and dynamic 4-point bend testing in accordance with ASTM F382, Standard Specification and Test Method for Metallic Bone Plates. The results demonstrate that the modified components are substantially equivalent to the predicate.

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
% Mr. Ed. Boehmer
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

JAN - 4 2011

Re: K102998
Trade/Device Name: Congruent Bone Plate System
Regulation Number: 21 CRF 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: October 6, 2010
Received: October 8, 2010

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. 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

K102998

4. Indications for Use

JAN – 4 2011

510(k) Number (if known): K102998

Device Name: Congruent Bone Plate System

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Prescription Use √ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102998