K120163 (1/2)

FEB 17 2012

6. 510(k) Summary

BioBridge®

Manufacturer:	ACUTE Innovations 21421 NW Jacobson Road, Suite 700 Hillsboro, OR 97124
Contact:	Mrs. Mariah Knight Regulatory and Quality Manager Phone: (503) 686-7200 ext 3300
Date Prepared:	January 12, 2012

DEVICE INFORMATION

Trade/Proprietary Name	BioBridge® Plating System
Common Name:	Plate, fixation system
Classification:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories
Class:	II
Product Code:	HRS
Predicate:	K081588 Re-Zorb Plating System (Acute Innovations) (now called BioBridge® Plating System)

Indications For Use:
General Indications:
In the presence of appropriate additional immobilization or fixation, indicated for maintaining the alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, and maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures.
Specific indications:

1. Metacarpus, proximal and middle phalangeal bones
2. Long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax

Device Description:
The BioBridge® Plating system, originally cleared under K081588, consists of plates and fixation devices used:

General indications:
In the presence of appropriate additional immobilization or fixation, indicated for maintaining the alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, and maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures.
Specific indications:

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The purpose of this Special 510k is to expand the plate sizing and geometry options, and to add a marketing claim. The addition of the plate sizes and geometries are intended to give the user more options to better accommodate varying patient anatomy and varying surgical situations. There are 51 additional plates of varying lengths, widths, thicknesses and contours. The modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device. The added marketing claim is designed to highlight the products use in reconstructive procedures of the thorax which is already covered by the specific indications for use of the predicate device.

Comparison to Predicate Device:
The BioBridge® Plating System with these line extensions is substantially equivalent to the predicate previously cleared in K081588 with respect to indications, function, and type of materials and processing. The added marketing claim is substantially equivalent to the predicate system as it is covered by the previously cleared indications for use. None of the changes raise any new issues of safety or efficacy.

Design Controls/Mechanical Performance:
Risk analysis was conducted on the device modifications as part of the Design Control activities. A worst case analysis of the bending strength, 4-point bend testing, and simulated use testing of the plate additions was conducted. The results demonstrated that the acceptance criteria defined in the Design Control Activities Summary were met.

Conclusion:
The data and information provided in this submission support the conclusion that BioBridge® Plating System with its line extensions and added marketing claim is substantially equivalent to its predicate device, BioBridge® Plating System, cleared under K081588 with respect to indications for use and technological characteristics.

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

FEB 17 2012

Acute Innovations, LLC.
% Ms. Mariah Knight
Regulatory and Quality Manager
21421 NW Jacobson Road, Suite 700
Hillsboro, Oregon 97124

Re: K120163
Trade/Device Name: BioBridge® Plating 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: January 12, 2012
Received: January 19, 2012

Dear Ms. Knight:

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,

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

Enclosure

5. Indications for Use

510(k) Number (if known): K120163

Device Name: BioBridge® Plating System

General Indications:

In the presence of appropriate additional immobilization or fixation, indicated for maintaining the alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts, and maintenance of relative position of weak bony tissue (e.g., bone grafts, bone graft substitutes, or bone fragments from comminuted fractures), in trauma and reconstructive procedures.

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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)

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

510(k) Number K120163