ACUTE Innovations® LLC 21421 NW Jacobson Road, Suite 700, Hillsboro, OR 97124
Section 5: 510(k) Summary Phone: (503) 686-7200 Fax: (503) 549-8959

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.

June 2, 2008

SEP - 3 2008

Submitter Information:
Acute Innovations LLC
21421 N.W. Jacobson Road, Suite 700
Hillsboro, OR 97124-9432
Phone: (503) 686-7200
FAX: (503) 549-8959
Contact: Alyssa Thomas, Regulatory Specialist

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

Common Name:
Plate, Fixation, Bone

Proprietary Name:
Re-Zorb™ Plating System

Proposed Regulatory Class:
Class II, 21 CFR 888.3030

Device Product Code:
HRS

Legally Marketed Equivalent Device(s):
Inion FreedomPlate™ (K 063410)

Intended Use:
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 include: 1. Craniofacial skeleton, cranium, mid-face, maxilla, and mandible, 2. Metacarpus, proximal and middle phalangeal bones, 3. Long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax.

The intended use is identical to the predicate device.

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Device Description:
The Re-Zorb™ Plating System consists of plates, fixation devices, and associated instrumentation. The plates are offered in lengths of 60 and 110mm, and widths of 14 and 20mm. All plates are 1.6mm thick with uniformly distributed fixation holes and a polished finished. Fixation devices included in the system consist of screws and tacks. The screws and tacks are offered in 2.7mm diameters and lengths ranging from 8 to 40mm. The plates, screws, and tacks are injection molded from poly (L-lactide-co-D, L-lactide) 70:30, which gradually lose strength in vivo and are provided sterile. Suture can also be used in conjunction with the plates.

Technological Characteristics:
Based on the performance data and specifications presented, it can be concluded that the Acute Innovations Re-Zorb™ Plating System has substantially equivalent intended use, scientific technology, degradation profile and mechanical properties to the predicate. The only difference to the predicate is the type of degradable material used, which has been shown through performance data and specifications not to raise any new questions of safety and effectiveness.

No applicable mandatory performance standards exist for this device. Compliance to voluntary consensus standards is listed in the application. Clinical and non-clinical tests are not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Acute Innovations, LLC
% Ms. Alyssa Thomas
Regulatory Specialist
21421 Northwest Jacobson Road
Hillsboro, Oregon 97124

SEP - 3 2008

Re: K081588
Trade/Device Name: Re-Zorb™ 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: June 3, 2008
Received: June 5, 2008

Dear Ms. Thomas:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 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): K081588

Device Name: Re-Zorb™ Plating System

Indication 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. Craniofacial skeleton, cranium, mid-face, maxilla, and mandible
2. Metacarpus, proximal and middle phalangeal bones
3. Long bones, flat bones, short bones, irregular bones, appendicular skeleton, and thorax

Prescription Use ___x___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use No. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)_____

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

510(k) Number K081588