Acute Innovations LLC 5885 NW Cornelius Pass Road, Suite 200, Hillsboro, OR 97124
Phone: (503) 686-7200 Fax: (503) 645-9304

K061206

JUN 19 2006

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: Acute Innovations LLC
5885 N.W. Cornelius Pass Road, Suite 200
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USA
Phone: (503) 686-7200
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Contact: Alyssa Thomas, Regulatory Specialist

Classification Name:	Smooth or threaded metallic bone fixation fastener
Common Name:	Screw, Fixation, Bone
Proprietary Name:	Acute Bone Screw
Proposed Regulatory Class:	Class II, 21 CFR 888.3040
Device Product Code:	HWC
Legally Marketed Equivalent Device(s):	Macropore OS Reconstruction System K024169 Acumed Cortical Bone Screw K942340

Device Description: The Acute Bone Screws consists of bone screws of varying lengths. The screws are partially and fully threaded, have a head with a hex drive, are cannulated or solid, and can be used with or without a plate or washer. The screws are manufactured out of titanium per ASTM F-136 and are provided non-sterile.

Intended Use: The Acute Bone Screw is a general purpose screw intended to stabilize and provide fixation for fractures, fusions, and osteotomies of the thorax (ribs, sternum, clavicle, scapula).

These are similar to intended use of predicate devices and do not raise new issues of safety and effectiveness.

Technological Characteristics: The Acute Bone Screws are made out of Titanium per ASTM F-136. The equivalent screw device listed for Acumed also use Titanium per ASTM F-136.

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

Based upon the similarities of the Acute Bone Screw and the predicate devices studied, the safety and effectiveness of the Acute Bone Screw is substantially equivalent to the predicate devices referenced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2006

Acute Innovations LLC
% Ms. Alyssa Thomas
Regulatory Specialist
5885 N.W. Cornelius Pass Road, Suite 200
Hillsboro, Oregon 97124-7200

Re: K061206
Trade/Device Name: Acute Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 20, 2006
Received: May 1, 2006

Dear Mr. 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for 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): _____

Device Name: Acute Bone Screw

Indications For Use:

The Acute Bone Screw is a general purpose screw intended to stabilize and provide fixation for fractures, fusions, and osteotomies of the thorax (ribs, sternum, clavicle, scapula).

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (Part 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 General, Restorative, and Neurological Devices

510(k) Number K061206