510(k) Summary

Manufacturer:	ACUTE Innovations, LLC 21421 NW Jacobson Road, Suite 700 Hillsboro OR, 20005 503.686.7200
Device Trade Name:	ACUTE Innovations Sternal Fixation System
Contact:	Ms. Mariah Knight Regulatory Representative
Prepared By:	Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street, NW, 12th Floor Washington, DC 20005 Phone: (202) 552-5800 Fax: (202) 552-5798
Classifications:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories and 21 CFR 888.3010, Bone fixation cerclage
Class:	II
Product Codes:	KTT, JDQ, and HWC

SEP 17 2010

Indications For Use:
The ACUTE Innovations® Sternal Fixation System is intended for use in the stabilization and fixation of fractures of the anterior chest wall, including sternal fixation following sternotomy and sternal reconstructive surgical procedures.

Device Description:
The ACUTE Innovations® Sternal Fixation System consists of plates and accessories as well as a cerclage-based device to provide fixation for sternotomies and sternal fractures. The plate designs for the Sternal Fixation System match the general anatomy of the sternum. The components of the ACUTE Innovations® Sternal Fixation System are made of commercially pure titanium, titanium alloy or stainless steel.

Predicate Devices:
Comparative information presented in the 510(k) supports the substantial equivalence of the ACUTE® Innovations Sternal Fixation System with respect to its indications for use, design, materials, and function.

This 510(k) demonstrates the substantial equivalence of the ACUTE Innovations® Sternal Fixation System to the following predicate devices: Acumed Cerclage Crimp Sleeve (K931246); KLS-Martin Sternal Plating System (K032413); Lorenz Sternal Closure System with Modular Screw (K011076); Synthes Sternal Reconstruction System (K052683, K031508).

The geometry of the subject plates matches that of the sternum and predicate sternal plates. The cerclage-based device has the same crimping mechanism as one of the predicate devices. The ACUTE Innovations® Sternal Fixation System and the predicate sternal fixation systems are made of the same materials. The methods of fixation for the subject device are the same as for the predicate devices. The non-clinical tests performed by the company included: an analysis of bending strength of the ACUTE Innovations® sternum plate and tensile testing of the cerclage-based device. Based on comparability to the predicate screws, no additional testing was performed on the stainless steel screws. The results of the performed tests demonstrate that the ACUTE® Innovations Sternal Fixation System is substantially equivalent to legally marketed predicate devices.

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

ACUTE Innovations, LLC
% Ms. Mariah Knight
Regulatory Representative
21421 NW Jacobson Road, Suite 700
Hillsboro, Oregon 20005

SEP 17 2010

Re: K101170
Trade/Device Name: ACUTE Innovations® Sternal Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT, JDQ, HWC
Dated: August 2, 2010
Received: August 4, 2010

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.

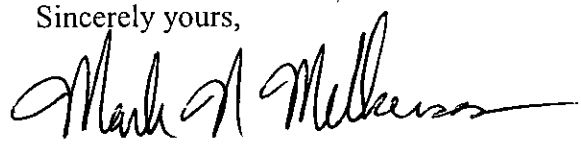
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

Enclosure

4. Indications for Use

K101170

SEP 17 2010

510(k) Number (if known): K101170 (pg 1/1)

Device Name: ACUTE Innovations® Sternal Fixation System

The ACUTE Innovations® Sternal Fixation System is intended for use in the stabilization and fixation of fractures of the anterior chest wall, including sternal fixation following sternotomy and sternal reconstructive surgical procedures.

Prescription Use ___√___ (Part 29 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (29 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K101170