510(k) Summary

NOV 19 2012

Contact Details

Applicant Name: Acumed LLC
5885 NW Cornelius Pass Road, Hillsboro, OR 97124-9432

Kara Budor, Regulatory Specialist
503-207-1412

Date Prepared: August 20, 2012

Device Name

Trade Name: Acumed Pelvic Bone Plate System

Common Name: Pelvic System

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

Class: II

Product Code: HRS

Legally Marketed Predicate Device(s)

There are two predicate devices. The comparison is to the Stryker Trauma Pelvic Set and the I.T.S. Pelvic Reconstruction System.

510(k) Number	Product Code	Trade Name	Applicant
K001614	KTW 888.3030	Stryker Trauma Pelvic Set	Howmedica Osteonics Corp.
K063166	HRS 888.3030	I.T.S. Pelvic Reconstruction System	I.T.S. Implantat-Technologie-Systeme GmbH

Device Description

The Acumed Pelvic Bone Plate System consists of plates, screws and accessories intended to provide fixation during fractures, fusions, and osteotomies of the acetabulum, sacrum, ilium,

and entire pelvic ring, as well as treatment of sacroiliac joint dislocations and symphysis pubis disruptions.

Plates are available in a variety of shapes and sizes which can be used "as is" or additionally contoured and/or trimmed intraoperatively to accommodate varying injury patterns and/or patient anatomy. All plates are made of titanium per ASTM F67 and are designed to accommodate the 3.5mm screws included in the system. Plates range in length from 30mm to 250mm, have a width of 4mm to 17mm, and a thickness of 1.5mm to 4mm.

The system includes 3 families of screws with different diameters: 2.7mm, 3.5mm, and 4.3mm. All screw families can be used for fixation independent of the plates. Screws are made of titanium alloy per ASTM F136.

All implants are provided sterile and non-sterile.

Intended Use/Indications for use

The Acumed Pelvic Bone Plate System consists of plates, screws and accessories intended to provide fixation during fractures, fusions, and osteotomies of the acetabulum, sacrum, ilium, and entire pelvic ring, as well as treatment of sacroiliac joint dislocations and symphysis pubis disruptions.

Substantial Equivalence Comparison

The basic comparison between the Acumed Pelvic Bone Plate System and the predicate devices is given in the table below.

Category	Acumed Pelvic Bone Plate System	I.T.S. Pelvic Reconstruction System K063166	Stryker Trauma Pelvic Set K001614
Material	Titanium per ASTM F67 and Titanium alloy per ASTM F136	Commercially pure titanium and 6-4 alloyed titanium	Stainless Steel per ASTM F138
Plate Shape	Straight plates Curved plates Plates for anatomy specific sites	Straight plates Curved plates Plates for anatomy specific sites	Straight plates Curved plates Plates for anatomy specific sites
Plate Fixation Method	Screw fixation	Screw fixation	Screw fixation
Screw Type	Non-locking	Non-locking and Locking	Non-locking
Provided sterile and/or non-sterile	Provided sterile and non-sterile	Unknown	Provided sterile and non-sterile
Implants are used with general surgical instrumentation	Yes	Yes	Yes

The Acumed Pelvic Bone Plate System, the I.T.S. PRS Low Profile – Multiple Type – Pelvic Plating System, and the Stryker Trauma Pelvic Set are all systems of plates, screws, and instruments which are used to achieve fixation. There are some differences, but none of them raise new issues of safety or effectiveness. The Acumed Pelvic Bone Plate System is substantially equivalent to the predicate devices.

Non-clinical Testing

The non-clinical testing included in this submission includes testing to ASTM F382 and F543.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 19, 2012

Acumed, LLC
% Ms. Kara Budor
Regulatory Specialist
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K122538
Trade/Device Name: Acumed Pelvic Bone Plate 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: August 20, 2012
Received: August 21, 2012

Dear Ms. Budor:

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.htmfor 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,

Erin I. Keith

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

Indications for Use

510(k) Number (if known): K122538

Device Name: Acumed Pelvic Bone Plate System

Indications for Use:

The Acumed Pelvic Bone Plate System includes plates, screws, and accessories designed to provide fixation during fractures, fusions, and osteotomies for the acetabulum, sacrum, ilium, and entire pelvic ring, as well as treatment of sacroiliac joint dislocations and symphysis pubis disruptions.

Prescription Use ___X___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K122538