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510(k) Summary
Sic Brevetti s.r.l., Device for Sternal Synthesis
(per 21CFR 807.92)

DEC - 8 2009

1. SUBMITTER/510(K) HOLDER

Sic Brevetti s.r.l.
Via Concesio, 325
00188 Rome
Italy

Contact Person: Gianfranco Panattoni, CEO
Telephone: 39.06.336.7948

Date Prepared: March 13, 2009

2. DEVICE NAME

Proprietary Name:	Device for Sternal Synthesis
Common/Usual Name:	Sternal fixation device
Classification Name:	Bone fixation cerclage, Accessory to suture, nonabsorbable, steel, monofilament and multifilament, sterile

3. PREDICATE DEVICES

- SternumFix Sternal Closure System (K063017)
- Flexigrip Sternal Closure System (K063009)
- Ethicon Stainless Steel Suture (K931271 and K946173)
- SuturTek Stainless Steel Suture (K063603)

4. DEVICE DESCRIPTION

The Device for Sternal Synthesis is a surgical implant that is available in two sizes manufactured of unalloyed titanium sheet. It is applied to the anterior surface of the sternum and inferior surfaces of the adjacent ribs on both the left and right sides of the sternum. It is circumferentially secured with monofilament surgical steel sutures.

5. INTENDED USE

The Device for Sternal Synthesis is indicated for closure and repair of the sternum after sternotomy to stabilize the sternum and promote fusion.

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6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

A claim of substantial equivalence is based on intended use, indications for use, design, materials, technological, and operational characteristics.

7. PERFORMANCE TESTING

Performance testing of the Device for Sternal Synthesis was performed in an artificial sternal model and demonstrated a significant difference in load to breakage and lateral displacement of reinforced and unreinforced sternal repairs.

Published data on testing of the Device for Sternal Synthesis in 45 patients undergoing cardiothoracic surgery with sternotomy who were at high risk for sternal wound complications revealed no intraoperative complications related to the DSS and a low incidence of postoperative sternal dehiscence typical of the post-operative course for patients with identified risk factors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Sic Brevetti S.r.l.
% Medical Device Consultants, Inc.
% Ms. Rosina Robinson
49 Plain Street
North Attleboro, MA 02760

DEC - 8 2009

Re: K090686
Trade/Device Name: Device for Sternal Synthesis (DSS)
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: II
Product Code: JDQ
Dated: November 11, 2009
Received: November 12, 2009

Dear Ms. Robinson:

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 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/cdrh/comp/ 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

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

Indications for Use

510(k) Number (if known): K090686

Device Name: Sic Brevetti s.r.l., Device for Sternal Synthesis (DSS)

Indications for Use:

The Device for Sternal Synthesis is indicated for closure and repair of the sternum after sternotomy to stabilize the sternum and promote fusion.

Prescription Use __X_____ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K090686