K 063009 – Flexigrip Sternal Closure System
510(k) Summary of Safety and Effectiveness Information

Company Name, Address and Contacts

Praesidia, S.r.l.
Via del Lapidari, 19
Bologna
40129 Italy
Telephone: 39 51 321238
Contact Person: Piero Malobbia

DEC 2 7 2006

Application Correspondent

Sternal Closure Systems Medical Products, Inc.
1083 Delaware Avenue
Buffalo, NY 14209
Telephone:

Establishment Registration Number: Not applicable

Device Information

Proprietary Name:	Flexigrip Sternal Closure System
Common Name:	Cerclage bone fixation
Classification Name:	Bone fixation, cerclage
Classification Panel:	Orthopedic
Classification:	21CFR888.3010
	87JDQ
Class:	II

Substantial Equivalence:

Pioneer Surgical Technology, Cerclage cable with hex button, K974016
Synthes (USA), Synthes sterile sternal fixation system, K050041
Kinamed Inc., Iso-Elastic Cerclage System, K030256
Metagen, Activelock Wire Cerclage System, K983976
Standard sternal wires, 510(k) not applicable due to preamendment status

Device Description

The device consists of a specially shaped clip made of shape memory metal alloy, Nitinol, which is malleable at 10°C and returns to its original shape and stiffness at 27°C. The clip is open on one side and is expanded when cold, placed around the sternum, and returns to shape when warm clamping the sternum together. It is made in a series of 9 sizes from 20 to 40 mm across and 11 to 14 mm deep. The material conforms to the ASTM F2063-05 standard for shape memory alloys and is supplied sterile. Appropriate

surgical instruments are also supplied to allow for proper sizing and placement of the clip around the sternum.

The Flexigrip Sternal Closure System operates in generally the same manner as stainless steel sutures or any of the listed predicate devices in that it holds the surfaces of the surgically split sternum together after open chest surgery allowing the sternum to heal. Nitinol has a long history of successful implantation in orthopedic and cardiovascular applications dating back to the mid-1970's. The major difference between this device and the predicate devices is that this device does not completely encircle the sternum.

Intended Use

The Flexigrip Sternal Closure System is intended for use in closure or repair of the sternum after sternotomy, fracture or dehiscence.

Summary of Technological Characteristics

Characteristic	Flexigrip	Activelock	Iso-Elastic	Synthes	Pioneer	Surgical Wire
Material(s)	Nitinol	CoCr & Nitinol	Polymeric with metal clamp	Titanium & TiAlNb Alloy	Stainless Steel (can be silver coated)	Stainless steel
Full Cerclage	No	Yes	Yes	No	Yes	Yes
Special Tools	Yes	Yes	Yes	Yes	Yes	No
Configuration	Solid wire	Solid wire and clamp	Polymeric cable and metal clamp	Plate and screw system	Braided wire cable with metal crimp	Braided wire
Clamp Method	NA	Special clamp	Special clamp	NA	Crimp	Twisted
Sternal Closure Only	Yes	No	No	Yes	Yes	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Praesidia, S.r.l.
% Sternal Closure Systems Medical Products, Inc.
Mr. George Haar
General Manager
1083 Delaware Avenue
Buffalo, New York 14209

DEC 27 2006

Re: K063009
Trade/Device Name: Flexigrip Sternal Closure System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ, HRS
Dated: September 29, 2006
Received: October 3, 2006

Dear Mr. Haar:

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) 276-0210 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): K063009

Device Name: Flexigrip Sternal Closure System

Indications For Use: The Flexigrip Sternal Closure System is intended for use in closure or repair of the sternum after strenotomy, fracture or dehiscence.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

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

510(k) Number K063009