K053624 (pg 1)

510(K) SUMMARY

Submitter:	Medicon. E.G. Gaensaecker 15 Tuttlingen, D-78532 Germany Phone: 011-49-7462-20090 Fax: 011-49-7462-2009-9956
Contact Person:	Andreas Burger
Date Prepared:	December 20, 2005
Trade Name:	Stern-a-Fix Sternal Closure System
Common Name:	Plate, Fixation, Bone
Classification Name and Number:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 880.3030, Product Code HRS)
Regulatory Class:	Class II
Predicate Devices:	• KLS-Martin Sternal Plating System, K032413 • Lorenz Sternal Closure System with Modular Screw, K011076 • Lorenz Sternal Closure System, K033740
Description:	The Medicon Stern-a-Fix Sternal Closure System consists of titanium plates and 2.4 mm locking and standard bone screws, as well as 2.7 mm emergency screws. All 2.4 mm screws are self-drilling, i.e., a predrilled hole is not required, but may be used if desired. Screws are provided in lengths from 7-15 mm. The plates are affixed to the sternum using the screws. They include thinner horizontal sections to facilitate quick re-entry.
Intended Use:	The Medicon Stern-a-Fix Sternal Closure System is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.
Substantial Equivalence:	The Medicon Stern-a-Fix Sternal Closure System is the same as the predicate devices in indicated use, method of rigid bone fixation, operating principle and materials. Fixation strength of the Medicon Stern-a-Fix bone plate for sternal closure was compared to cerclage wire on the basis of the study "Lower Sternal Reinforcement Improves the Stability of Sternal Closure", by Dasika *et al.* Significantly greater stability was recorded for the Medicon Stern-a-Fix sternal closure system in all regions of the sternum, particularly at the xyphoid.

JUL 17 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2006

Medicon, E.G.
% Business Support International
Ms. Angelika Scherp
Regulatory Consultant
AMSTEL 320-I
Amsterdam
Netherlands 1017AP

Re: K053624
Trade/Device Name: Medicon Stern-a-Fix Closure System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: June 6, 2006
Received: June 14, 2006

Dear Ms. Scherp:

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.

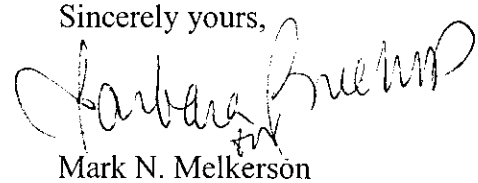
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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): K053624

Device Name: Medicon Stern-a-Fix Sternal Closure System

Indications for Use:

The Medicon Stern-a-Fix Sternal Closure System is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

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 General, Restorative, and Neurological Devices

510(k) Number K053624