K030378

Page 1 of 1

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
Stryker Leibinger Cranial Fixation System

MAR 2 0 2003

General Information

Proprietary Name:	Stryker Leibinger Cranial Fixation System
Common Name:	Plate, Cranioplasty, Pre-formed, Non-Alterable
Proposed Regulatory Class:	Class II
Device Classification:	GXN 882.5330, Plate, Cranioplasty, Preformed, Non- Alterable
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 269-323-4226
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Wade T. Rutkoskie Associate Manager RA QA Phone: 269-323-4226 Fax: 269-323-4215

Intended Use

The Stryker Leibinger Cranial Fixation System is intended for the fixation of a cranial bone flap after a craniotomy. The implant could be applied in the craniotomy gap as well as in burr holes.

Substantial Equivalence

EQUIVALENT PRODUCTS:

The Stryker Leibinger Cranial Fixation System is substantially equivalent to the Leibinger Quik Disk Titanium Clamp System (K993990), Aesculap Craniofix Titanium Clamp System (K972332), the Synthes Cranial Flap Twist Clamp (K991860) and the Walter Lorenz RapidFlap Cranial Clamp (K991029).

Wade T. Rutkoskie

Wade T. Rutkoskie
Associate Manager RA QA
Stryker Instruments
Leibinger Division

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Mr. Wade T. Rutkoskie
Associate Manager RA QA
Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49087

Re: K030378
Trade/Device Name: Stryker® Leibinger Cranial Fixation System
Regulation Number: 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: II
Product Code: GXN
Dated: February 4, 2003
Received: February 5, 2003

Dear Mr. Rutkoskie:

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.

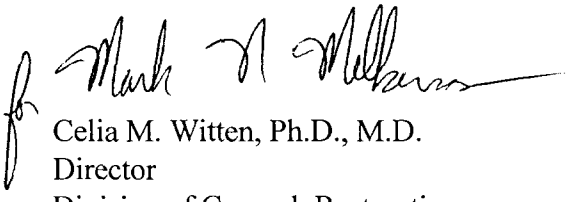
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030378

Device Name: Stryker® Leibinger Cranial Fixation System

Indication For Use:

The Stryker® Leibinger Cranial Fixation System is intended for the fixation of a cranial bone flap after a craniotomy. The implant could be applied in the craniotomy gap as well as in burr holes.

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

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use_____ or Over-The-Counter Use_____
(per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhern

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510(k) Number K030378