K052871/S1

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:

Stryker® Custom Ti Implant

DEC 16 2005

General Information

Proprietary Name:	Stryker® Custom Ti Implant
Common Name:	Preformed Plate
Proposed Regulatory Class:	Class II
Device Classification:	GXN (21 CFR 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 Manager, RA/QA Phone: 269-323-4226 Fax: 269-323-4215
Summary Preparation Date:	October 4, 2005

Intended Use

The Stryker® Custom Ti Implant is a titanium or titanium-mesh implant that is designed to custom-fit a patient's defect. This implant will utilize patient C.T. scan data to produce a custom-contoured titanium or titanium mesh implant that optimally fits each patient. The unique process of developing a Stryker® Custom Ti Implant converts patient CT-Scan data into 3-D images. These images are used to create anatomical models which are then used to build the customized implant.

Substantial Equivalency Information

The Stryker® Custom Ti Implant is substantially equivalent to the Stryker Custom Cranial Implant (K043250) and Synthes (USA) Patient Specific Cranial/Craniofacial Implants (K033868). The Stryker Custom Ti Implants will be manufactured using the same method as the Stryker Custom Cranial Implant (K043250) using titanium or titanium mesh similar to the Synthes (USA) Patient Specific Cranial/Craniofacial Implants (K033868).

The implant will be designed and molded for each patient to correct trauma and/or defects in mandibular, maxillofacial, or craniofacial bone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Mr. Wade T Rutkoskie
Stryker Leibinger
4100 East Milham Ave
Kalamazoo, Michigan 49001

Re: K052871
Trade/Device Name: Stryker Custom Ti Implant
Regulation Number: 21 CFR 882.5330
Regulation Name: Plate, Cranioplasty, Preformed, non-alterable
Regulatory Class: II
Product Code: GXN
Dated: November 9, 2005
Received: November 22, 2005

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 (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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052871/S

510(k) Number (if known): K

Device Name: Stryker Custom Ti Implant

Indications For Use:

The Stryker® Custom Ti Implant is designed individually for each patient to correct trauma and/or defects in mandibular, maxillofacial or craniofacial bone.

Prescription Use X AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (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)

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

510(k) Number K052871

(Posted November 13, 2003)