MAR 17 2005

K050535

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:

Stryker® MMF Screw

General Information

Proprietary Name:	Stryker® MMF Screw
Common Name:	Small Bone Screws
Proposed Regulatory Class:	Class II
Device Classification:	76 DZL 21 CFR 872.4880, Intraosseous Fixation Screw or Wire
Submitter:	Stryker® Instruments Leibinger Micro Implants 4100 East Milham Avenue Kalamazoo, MI 49001 877-534-2464 x 4062
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Nathan M. Miersma Regulatory Affairs Representative Phone: 877-534-2464 x 4062 Fax: 269-323-4215

Intended Use

The Stryker® MMF Screw is intended for use as a bone screw in the temporary maxillomandibular fixation to provide indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.

Substantial Equivalence

EQUIVALENT PRODUCTS:

The Stryker® MMF Screw is substantially equivalent to the Leibinger® IMF Screw, K963030 (Howmedica Leibinger).

Nathan M. Miersma
Regulatory Affairs Representative
Stryker®
Instruments
Leibinger Micro Implants Division

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

Stryker® Instruments
Mr. Nathan M. Miersma
Regulatory Affairs Representative
Stryker Instruments, Leibinger Division
4100 East Avenue
Kalamazoo, Michigan 49001

Re: K050535
Trade/Device Name: Stryker® MMF Screw
Regulation Number: 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: March 1, 2005
Received: March 2, 2005

Dear Mr. Miersma:

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.

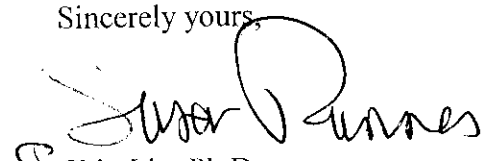
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050535

Device Name: Stryker® MMF Screw

Indications For Use:

The Stryker® MMF Screw is intended for use as a bone screw in temporary maxillomandibular fixation, providing indirect stabilization of fractures of the maxilla, mandible or both, where there is sufficient occlusion.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 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)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K050535