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Craniomaxillofacial

510(k) Summary of Safety and Effectiveness:

Stryker Resorbable Fixation System

- Proprietary Name:** Stryker Resorbable Fixation System
- Common Name:** Resorbable Bone Plating System
- Classification Name and Reference:** *Sec. 888.3030* - Single/multiple component metallic bone fixation appliance and accessories
- Proposed Regulatory Class:** Class II
- Product Codes:** HRS, MAI, EZX, DZJ and HWC
- Predicate Device:**
 - Stryker Leibinger Resorbable Fixation System – **K993061**
 - Lactosorb 1.5mm Implants – Mesh Panels – **K971870**
 - Stryker Neuro II 0.3mm Titanium Mesh – **K983528**

For Information contact:

Manish Patel
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Date Prepared:

10/18/2011

Description:

This Special 510(k) is being submitted to the U.S. FDA to provide authorization to market modifications to the Stryker Leibinger Resorbable Fixation System cleared under K993061.

Proposed Modification:

The subject Stryker Resorbable Fixation System has the same intended use and indications for use, is constructed from the same material, and has the same fundamental scientific technology as the previously cleared Leibinger Resorbable Fixation System under K993061.

The only changes are below

1. Addition of a 0.5 mm Low Profile Mesh to an already existing 0.7 mm size range
2. Increase in thread pitch of screws
3. Increase in thread pitch of standard and self-drilling taps

Device Description:

The Stryker Delta Resorbable Fixation System is a cranio-maxillofacial plating system, intended for use in the fixation of bones of the craniofacial and midfacial skeleton affected by trauma or reconstruction. The system can be used in both adult and pediatric patients but is not intended for use in mandible and/or full load bearing procedures. It consists of resorbable bone fixation plates, meshes and screws made of a copolymer of poly lactide and poly glycolide. The copolymer degrades and resorbs in vivo by hydrolysis into lactic and glycolic acid which are metabolized in the body to water (H₂O) and carbon dioxide (CO₂). The Delta Resorbable Fixation System is color coded and currently offered in two diameters, 1.7 mm and 2.2 mm with an emergency screw option of 2.6 mm. As the resorbable bone fixation plates and other devices already cleared in the earlier submission have not been modified, they are not described in this Special 510(k).

Intended Use / Indications for Use:

The Stryker Resorbable Fixation System is intended for use in the fixation of bones of the craniofacial and midfacial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients but is not intended for use in the mandible and/or full load bearing procedures.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker
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DEC 23 2011

Re: K113109
Trade/Device Name: Stryker Resorbable Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, MAI, EZX, DZJ, HWC
Dated: December 2, 2011
Received: December 5, 2011

Dear Manish Patel:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

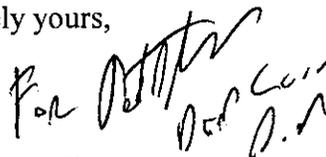
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style and is positioned above the typed name.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113109

Device Name: Stryker Resorbable Fixation System

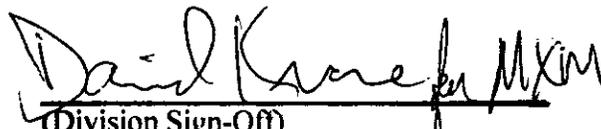
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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113109