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510(k) Summary of Safety and Effectiveness:

Stryker® Patient Specific Polymer Implant

OCT 2 6 2010

Proprietary Name:	Stryker® Patient Specific Polymer Implant
Common Name:	Preformed Alterable Cranioplasty Plate , PMMA
Classification Name and Reference:	Polytetrafluoroethylene with carbon fibers composite implant material, 21 CFR §878.3500 Preformed alterable cranioplasty plate 21 CFR §882.5320
Proposed Regulatory Class:	Class II
Product Codes:	KKY, GWO
For Information contact:	Stephanie M. Fitts, PhD Director, Regulatory Affairs and Regulatory Compliance Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5405 Fax: (201) 831-4405
Date Prepared:	October 8, 2010

Description:

This Special 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the Stryker® Patient Specific Polymer Implant components in a sterile fashion.

Intended Use:

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

Proposed Modification:

The product will now be supplied sterile via gamma radiation in packaging that has been validated to maintain sterility throughout the product's labeled shelf-life. The manufacturing location will change from the contract manufacturer to Stryker. Although the manufacturing process has not changed since originally described in K043250, newer versions of the commercially available software described in the original submission (Materialise software) have been integrated into the process with full validation.

Device Description:

The Stryker® Patient Specific Polymer Implant is a pre-formed plate made of cured Simplex P bone cement that is shaped to match a specific patient's bony defect based on CT scans provided by the surgeon. The plate is fixed into place using compatible Stryker plate and screw systems.

Summary of Data:

Testing has been performed to demonstrate equivalence of the subject sterile devices to the predicate non-sterile devices. The testing includes sterilization validation via ISO 11137-2, and pyrogenicity testing via the LAL test according to ANSI/AAMI ST72:2002. Bioburden testing was conducted to ISO 11137-2. The packaging has been validated to ensure that sterility is maintained throughout the product's labeled shelf life of 6 months.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corporation
% Stephanie M. Fitts, PhD
Director, Regulatory Affairs and
Regulatory Compliance
325 Corporate Drive
Mahwah, New Jersey 07430

OCT 26 2010

Re: K103010
Trade/Device Name: Stryker® Patient Specific Polymer Implant
Regulation Number: 21 CFR 878.3500
Regulation Name: Polytetrafluoroethylene with carbon fibers composite implant material
Regulatory Class: II
Product Code: KKY, GWO
Dated: October 8, 2010
Received: October 12, 2010

Dear Dr. Fitts:

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 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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,

For Peter Thomas DE/Dir

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

Enclosure

OCT 2 6 2010

Indications for Use

510(k) Number (if known): K103010

Device Name: Stryker® Patient Specific Polymer Implant

Indications for Use:

The Stryker® Patient Specific Polymer 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 _____

(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)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103010