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510(k) Summary

JUL 14 2011

Name and Address of Sponsor:	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
510(k) Contact Person:	Claudia Wiesemann Stryker Leibinger GmbH & Co. KG Bötzinger Straße 41 D-79111 Freiburg Germany Phone: (+49) 761 45 12 4093 Fax: (+49) 761 4512 49 283 Email: claudia.wiesemann@stryker.com
Date Summary Prepared:	April 14, 2011
Device Trade 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 Code:	KKY, GWO

Description:
This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the Stryker® Patient Specific Polymer Implant components with an online ordering system.

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.

Proposed Modification:
The product will now be supplied with an online ordering system called eRequest Lifecycle. The manufacturing location and processes have not changed since originally described in K103010.

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.

Substantial Equivalence:
The Stryker® Patient Specific Polymer Implant has been verified and validated according Stryker procedures for product design and development. The validation proves the safety and effectiveness of

the system. The information provided by Stryker in this 510(k) application was found to be substantially equivalent with predicate devices such as the 510(k) clearance of:

- Stryker® Patient Specific Polymer Implant (K103010)
- MEDPOR Customized Surgical Implant (K083621)

The following matrix demonstrates the substantially equivalence of the Stryker® Patient Specific Polymer Implant with the two predicates (K103010 and K083621).

	Stryker® Patient Specific Polymer Implant	**Stryker® Patient Specific Polymer Implant**	**MEDPOR Customized Surgical. Implant**
	Subject Device	Predicate Device I	Predicate Device II
510(k) Number		K103010	K083621
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.	The Stryker Patient Specific Polymer Implant is designed individually for each patient to correct trauma and/or defects in mandibular, maxillofacial, or craniofacial bone.	The MEDPOR Customized Surgical Implant is intended for the augmentation or restoration of bony contour in craniofacial defects.
Product Code	KKY, GWO	KKY, GWO	JOF, GWO
Material/Chemical composition	Simplex P Bone Cement	Simplex P Bone Cement	A linear, high-density polyethylene biomaterial
Ordering System			
Request Initiation			
Fax/Mail Order	X	X	X
Online Order	X	-	X
Image Data Transfer			
CD on disk via mail	X	X	X
Online Upload (Password protected)	X	-	X
Design Approval			
Fax/Mail Approval	X	X	X
Online Approval (Password protected)	X	-	X
Online assessment of virtual implant	X	-	X
Use of CT scans	X	X	X

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Howmedica Osteonics Corp. dba Stryker Orthopedics
c/o Ms. Claudia Wiesemann
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, NJ 07430

JUL 14 2011

Re: K111065
Trade/Device Name: Stryker® Patient Specific Polymer Implant
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate
Regulatory Class: Class II
Product Code: GWO, KKY
Dated: April 14, 2011
Received: April 18, 2011

Dear Ms. Wiesemann:

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,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K111065

Indications for Use

510(K) Number (if known): K111065

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____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111065