K103124 #4/4

Summary of Safety and Effectiveness
Series II X3® Large Diameter Acetabular Inserts

NOV 19 2010

Proprietary Name:	Series II X3® Large Diameter Acetabular Inserts
Common Name:	Hip prosthesis
Classification Name and Reference:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353 Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis, 21 CFR §888.3358 Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3350
Regulatory Class:	Class II
Product Codes:	87 MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate 87 LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented 87 LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented 87 JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented
Predicate Devices:	Series II X3® Acetabular Inserts and Trident® X3® Acetabular Insert
For Information contact:	Estela Celi, Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-6461 Fax: (201) 831-6038 estela.celi@stryker.com
Date Prepared:	October 21st, 2010

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Description

This Special 510(k) submission is a line extension to address modifications made to the Series II X3® Acetabular Inserts. The modifications made to the previously cleared Series II X3® Acetabular Inserts (K052748) are as follows: new larger head sizes, an alternate 4mm lateralization (with 0 and 10 degree hood), and additional 0 degree hood design to the existing 6mm lateralization.

Intended Use

The Series II X3® Large Diameter Acetabular Insert is a sterile, single-use device intended for the replacement of the bearing and/or articulating surfaces of the acetabulum to relieve pain and the restriction of motion.

Indications for Use:

The Series II X3® Large Diameter Acetabular Inserts are single use sterile components, intended for use in conjunction with an associated Howmedica Osteonics metal acetabular shell, femoral bearing, and femoral hip stem as part of a cemented or cementless total hip arthroplasty.

1) Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis.
2) Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3) Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4) Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Substantial Equivalence:

The Series II X3® Large Diameter Acetabular Inserts are substantially equivalent to the Series II X3® Acetabular Inserts cleared under K052748 and Trident® X3® Large Diameter Acetabular Inserts cleared under K062419 in regards to intended use, design, materials, and operational principles as a hip prosthesis.

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Substantial Equivalence Table with comparison of Technological Characteristics:

Series II Comparison of Subject to Predicate			
	Series II X3® Large Diameter Acetabular Inserts	**Series II X3® Acetabular Inserts**	**Trident® X3® Large Diameter Acetabular Insert**
510(k)	Pending	K052748	K062419
Product Type	Polyethylene Insert Components for Total Hip Arthroplasty	Polyethylene Insert Components for Total Hip Arthroplasty	Polyethylene Insert Components for Total Hip Arthroplasty
Intended Use	Painful, disabling joint disease of the hip resulting from: non-inflammatory degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis; revision of previous failed femoral head replacement, cup arthroplasty or other procedure; clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results; and where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.	Painful, disabling joint disease of the hip resulting from: non-inflammatory degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis; revision of previous failed femoral head replacement, cup arthroplasty or other procedure; clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results; and where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.	Painful, disabling joint disease of the hip resulting from: non-inflammatory degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis; revision of previous failed femoral head replacement, cup arthroplasty or other procedure, clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results, where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum
Anatomical Placement	Hip – Acetabular Bearing surface	Hip – Acetabular Bearing surface	Hip – Acetabular Bearing surface
Sizes Standard	0°, 10° 26mm to 44mm ID	Similar Hood Angle Similar Inner Diameter	Similar Hood Angle Similar Inner Diameter
Sizes Eccentric	0°, 10° 4 & 6mm lateralization 26mm to 44mm ID	Similar Hood Angle Similar Lateralization Similar Inner Diameter	N/A
Compatible Acetabular Shells	Secur-Fit, Secur-Fit Xtra, Omnifit, PSL, Dual Geometry, Microstructured, Osteonics HA Threaded	Secur-Fit, Secur-Fit Xtra, Omnifit, PSL, Dual Geometry, Microstructured, Osteonics HA Threaded	Trident Hemispherical Solid Back Shells, Trident PSL HA Solid Back Shells, Trident Hemispherical Cluster Shells, Trident PSL HA Cluster Shells, Trident Hemispherical Multi-Hole Shells
Insert Component Material	UHMWPE	UHMWPE	UHMWPE
Locking Mechanism	Snap-fit mechanism	Snap-fit mechanism	Press-Fit Mechanism
Minimum Nominal Dome Thickness	6.43 mm	5.56 mm	3.8 mm
Sterilization Method	Gas Plasma	Gas Plasma	Gas Plasma

Summary of Non-Clinical Testing and Evaluation:

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA).The risk analysis was performed according to the requirements of ISO 14971:2007 "Medical Devices - Application of risk management to medical devices". Records of the risk analysis process are retained in the design history file.

Predicate preclinical testing that was performed:
1) Lever Out Testing (Series II X3® and Trident® X3® Large Diameter)
2) Push Out Testing (Series II X3® and Trident® X3® Large Diameter)
3) Evaluation of Wear Characteristics (Trident® X3® Large Diameter)

Based upon the fact that the new Series II X3® Large Diameter Acetabular Inserts represent a line extension of the current Series II X3® Acetabular Inserts the following preclinical testing/evaluation was preformed:

Preclinical evaluations performed for the new Series II X3® Large Diameter Acetabular Inserts:
1) Poly thickness analysis (Series II X3® and Series II X3® Large Diameter)
2) Engineering analysis of locking mechanism (Series II X3® and Series II X3® Large Diameter)
3) Engineering analysis of inner diameter, head center, and liner head clearance (Series II X3® Large Diameter)

The results of the above testing verify that the new device is substantially equivalent to the predicate device.

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

Stryker Corporation
% Ms. Estela Celi
325 Corporate Drive
Mahwah, New Jersey 07430

NOV 19 2010

Re: K103124
Trade/Device Name: Series II X3® Acetabular Inserts
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI, LZO, MEH
Dated: October 21, 2010
Received: October 22, 2010

Dear Ms. Celi:

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,

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): K103124

NOV 19 2010

Device Name: Series II X3® Large Diameter Acetabular Inserts

Indications for Use:

The Series II X3® Large Diameter Acetabular Inserts are single use sterile components, intended for use in conjunction with an associated Howmedica Osteonics metal acetabular shell, femoral bearing, and femoral hip stem as part of a cemented or cementless total hip arthroplasty.

The indications for use of total hip replacement prostheses include:

1) Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis, or late stage avascular necrosis.
2) Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3) Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
4) Where bone stock is of poor quality or inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

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)

for MKM

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

510(k) Number K103124