K100933

9. 510(K) SUMMARY

OCT 6 2010

Sponsor Name: Consensus Orthopedics, Inc.
1115 Windfield Way, Suite 100
El Dorado Hills, CA 95762

510(k) Contact: Matthew M. Hull, RAC
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Date Prepared: 1 October 2010

Trade Name: CS2™ Plus Acetabular Insert

Common Name: Cross Linked Polyethylene, Lateralized, Acetabular Insert

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358, Product Code LPH)

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353, Product Code LZO)

Regulatory Class: Class II

Device Classification Panel: Orthopedic Devices

Predicate Device Identification:
The intended use, materials, and design features of the subject CS2™ Plus acetabular insert are substantially equivalent to those of predicate devices manufactured by Consensus Orthopedics and competitors (Table 9.1). The safety and effectiveness of the CS2™ Plus insert are adequately supported by the substantial equivalence information and materials data provided within this Special 510(k) submission.

Table 9.1: Predicate device summary table.

510(k) Number	Trade Name	510(k) holder	510(k) Clearance Date
K922561	Consensus™ Total Hip System	Consensus Orthopedics, Inc.	07/21/1993
K990135	Trilogy Acetabular System Longevity Crosslinked Polyethylene	Zimmer, Inc.	07/12/1999
K994415	Marathon Cross-linked Polyethylene Acetabular Cup Liners	DePuy Orthopaedics, Inc.	02/03/2000
K001534	Pinnacle Acetabular Cup System	DePuy Orthopaedics, Inc.	06/12/2000

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K010171	Duraloc Acetabular Cup System, 36mm Marathon +4 Polyethylene Liner	DePuy Orthopaedics, Inc.	04/06/2001
K021466	Consensus Acetabular Insert, Cross-Linked Polyethylene (CS2™)	Consensus Orthopedics, Inc.	07/24/2002
K061253	Reflection 3 Acetabular System	Smith & Nephew	05/31/2006
K070061	36mm CoCr Femoral Head and 36mm Acetabular Insert (CS2™)	Consensus Orthopedics, Inc.	01/31/2007

Indications for use with the CONSENSUS® Hip System or UNISYN™ Hip System:

A) Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
B) Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
C) Proximal femoral fractures.
D) Avascular necrosis of the femoral head.
E) Non-union of proximal femoral neck fractures.
F) Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities

Acetabular components are indicated for cemented and cementless use.
Consensus femoral stems are indicated for cemented and cementless use.
UniSyn femoral stems are indicated for cementless use only.
HA coated implants are indicated for cementless use only.

Device Description:
The Consensus® Hip System (CHS) currently offers a semi-constrained metal-backed acetabular component comprising a porous coated shell manufactured from Titanium alloy (ASTM F620 or F136) (K922561, K020153, K060635) and a mating insert manufactured from ultra-high molecular weight polyethylene (UHMWPE) (K922561) (ASTM F648) or highly crosslinked UHMWPE (ASTM F648) (K021466, K070061). The shell is designed for uncemented press-fit or cemented use to the prepared acetabulum, and is designed to mate with the insert via secure insert/shell locking mechanism. The previously cleared inserts are designed to articulate with the CHS femoral heads.

The CS2™ Plus acetabular insert adds a lateralized configuration to the current line of CHS crosslinked UHMWPE acetabular inserts (i.e. CS2™ inserts) (K021466, K070061). The design intent is to allow the surgeon more intraoperative flexibility to medialize the acetabular cup or lateralize the head center, while maintaining substantial insert wall thickness.

Comparison of Technological Characteristics:
The following features are common for the CS2™ Plus insert and the previously cleared CS2™ insert:

- Manufactured from DePuy Marathon® crosslinked UHMWPE (ASTM F648, (K994415).
- Compatible with previously cleared CHS acetabular shells (K922561, K020153, K060635), CHS femoral stems (K922561, K933499, K935453, K935193), CHS femoral heads (K953792, K960156, K030151, K070061), and UniSyn™ Hip System components (K003649, K062383) of the appropriate size.
- Identical articular surfaces designed to mate with 28mm, 32mm, and 36mm diameter femoral heads.
- 28mm ID inserts accommodate the same number of shell sizes.
- Neutral and hooded configurations.
    - Hooded configurations feature an identical Titanium X-ray marker (ASTM F136).
    - 28mm and 32mm inserts offer neutral or 20° hooded configurations.
- Minimum wall thickness at dome apex greater than 5mm.
- Identical insert/shell locking mechanism.
- Identical minimum intended range of motion.

The following features are unique to the CS2™ Plus insert in comparison to the previously cleared CS2™ insert:

- The CS2™ Plus insert is designed to position the femoral head center 5mm more laterally than that of the CS2™ insert.
- 32mm CS2™ Plus insert will accommodate two additional shell sizes (48 and 50mm OD), which are currently only compatible with 28mm CS2™ inserts.
- 36mm CS2™ Plus insert will accommodate two additional shell sizes (52 and 54mm OD), which are currently only compatible with 28mm and 32mm CS2™ inserts.
- Will not accommodate 22mm heads.
- 36mm CS2™ Plus inserts offer neutral or 10° hooded configurations, whereas the 36mm CS2™ inserts offer neutral, 10°, or 20° hooded configurations.
- The CS2™ Plus insert will have an increased wall thickness at the apex of the dome and beneath the external snap feature due to the 5mm lateral offset.
- When mated with the acetabular shell, the CS2™ Plus insert will extend further outside the shell by 5mm due to the 5mm lateral offset of the head center.

Summary of Nonclinical 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.

Based upon the fact that the new CS2 Plus Acetabular Inserts represent a line extension of the current CS2 inserts the following preclinical testing/evaluation was preformed:

1) Torsion testing of insert/shell locking mechanism (CS2 Plus & CS2)
2) Lever out testing (CS2 Plus & CS2)
3) Range of motion study (CS2 Plus & CS2)

4) CAD verification study of locking mechanism (CS2 Plus & CS2)
5) Push out testing (CS2)

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 W-O66-0609
Silver Spring, MD 20993-0002

Consensus Orthopedics, Inc.
% Mr. Matthew M. Hull, RAC
Director QS & RA
1115 Windfield Way Suite 100
El Dorado Hills, California 95762

OCT 6 2010

Re: K100933
Trade/Device Name: CONSENSUS® Hip System: CS2™ Plus Acetabular Insert
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, LZO
Dated: September 10, 2010
Received: September 15, 2010

Dear Mr. Hull:

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

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: K100933

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

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

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