MAY 19 2014

2. 510(k) SUMMARY

Sponsor Name:	Consensus Orthopedics, Inc. 1115 Windfield Way, Suite 100 El Dorado Hills, CA 95762
510(k) Contact:	Matthew M. Hull, RAC Phone: (916) 355-7156/ Fax: (916) 355-7190 mhull@consensusortho.com
Date Prepared:	21 April 2014
Trade Name:	Multi-Holed Shell for use with the CS2™ Acetabular Cup System
Common Name:	Acetabular Shell
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

Device Description:
The CS2 Acetabular Cup System consists of a shell and a mating insert. The acetabular component is designed for cemented or uncemented use. The acetabular shell is manufactured from titanium alloy (Ti 6Al-4V ELI, ASTM F620 or ASTM F136), with a porous coating of commercially pure titanium beads (CP Ti ASTM F-67).

The acetabular shells are available with or without screw holes in hemispherical or flared rim versions. The component has matching circumferential scallops on the shell and insert that rotationally secure the insert in the shell and allow for dialing the insert in a desired orientation. The shells with screw holes have up to 10 anatomically placed holes which accommodate optional bone screws to augment initial fixation. An optional apical dome hole plug and cement pod spacer are available. The acetabular insert is manufactured from ultra-high molecular weight polyethylene (UHMWPE, ASTM F648); highly cross linked polyethylene (UHMWPE, ASTM F648), or VitalitE (UHMWPE, ASTM F2695). They all feature a titanium alloy X-ray marker (Ti 6Al-4V ELI, ASTM F136).

The cancellous bone screws are manufactured from wrought titanium alloy (Ti 6Al-4V ELI, ASTM F136). The cancellous bone screws are 6.5mm diameter and have a low profile head with a hex drive recess. These are provided with certain versions of the acetabular shell for the option of additional fixation.

Indications for Use:
The CS2™ Acetabular Cup System is designed for use with the various hip systems manufactured by Consensus Orthpedics, Inc. The CONSENSUS® HIP SYSTEM, CS2™ HIP SYSTEM, and the TAPERSET™ HIP SYSTEM are designed for total or partial hip arthroplasty and is intended to be used with compatible components of the CONSENSUS® HIP SYSTEM.
The indications for use are:

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.

The CONSENSUS® hip stem is indicated for cemented or cementless use. The CS2™ and TAPERSET™ hip stems are indicated for cementless use.

The UNISYN™ HIP SYSTEM is indicated for significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis. Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.

A. Proximal femoral fractures.
B. Avascular necrosis of the femoral head.
C. Non-union of proximal femoral neck fractures.
D. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.

UNISYN™ stems used with roughened and plasma coated bodies are intended for cemented or uncemented use. UNISYN™ stems used with plasma/HA or HA coated bodies are intended for uncemented use only.

Substantial Equivalence:

Technological Characteristics/ Substantial Equivalence:
The intended use, materials, and design features of the subject Multi-Hole Shell for use with the CS2™ Acetabular Cup System are substantially equivalent to those of predicate devices manufactured by Consensus Orthopedics (Table 9.1). Previously cleared versions of the acetabular shell had from 3 to 5 screw holes, the new Multi-hole shell will offer options up to 10 screw holes. The safety and effectiveness of the Multi-hole Shell are adequately supported by the substantial equivalence information and materials data provided within this 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
K060635	Consensus Acetabular Shell System	Consensus Orthopedics, Inc.	04/28/2006

Legally Marketed Devices which are compatible:
K102399 (Consensus Orthopedics, Inc.) TAPERSET HIP SYSTEM
K030151 (Hayes Medical, Inc.) CONSENSUS HIP SYSTEM, UNISYN HIP SYSTEM
K935193 (U.S. Medical Products) Consensus' Hip System – Porous Coated Titanium Femoral Stem
K935453 (U.S. Medical Products) CONSENSUS(TM) HIP SYSTEM-HA COATED TITANIUM FEMORAL STEM
K933499 (U.S. Medical Products) CONSENSUS HIP SYSTEM- NON-POROUS TITANIUM FEMORAL STEM
K922561 (U.S. Medical Products) CONSENSUS(TM) TOTAL HIP SYSTEM
K070061 (Hayes Medical, Inc.) Consensus Hip System 36 mm CoCr Femoral Head
K953792 (U.S. Medical Products) CONSENSUS ZIRCONIA HEAD SIZE -3.5, 0, +5
K955386 (U.S. Medical Products) CONSENSUS ZIRCONIA FEMORAL HEAD
K960339 (U.S. Medical Products) CONSENSUS 22MM COCRMO FEMORAL HEAD
K960156 (U.S. Medical Products) CONSENSUS 32MM COCRMO FEMORAL HEAD
K960151(U.S. Medical Products) CONSENSUS 26MM COCRMO FEMORAL HEAD
K021466 (Hayes Medical, Inc.) CONSENSUS ACETABULAR INSERT, CROSS-LINKED POLYETHYLENE
K953198 (Hayes Medical, Inc.) CORTICELLOUS BONE SCREW
K100933 (Consensus) Consensus Acetabular insert, CS2 Plus
K110542 (Consensus) Consensus Biolox delta Ceramic Femoral Heads
K121263 (Consensus) TaperSet Hip System RDP Stem
K121935 (Consensus) TaperSet Hip System Small Stems
K120595 (Consensus) UniSyn Plus Hip Stem
K122512 (Consensus) CS2 Hip Stem
K130652 (Consensus) VitalitE Acetabular Insert

Non-Clinical Performance Data:

Engineering design evaluation of the additional screw holes being added to the acetabular shell shows that no additional biomechanical testing was required

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 19, 2014

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

Re: K141043
Trade/Device Name: Multi-Hole Acetabular Shell for the CS2™ Acetabular Cup System
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: April 21, 2014
Received: April 23, 2014

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

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Lori A. Wiggins

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

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K141043

Device Name: Multi-Hole Acetabular Shell for the CS2™ Acetabular Cup System

Indications for Use:

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

Elizabeth D. Frank -S
Division of Orthopedic Devices