2. 510(k) SUMMARY

DEC 17 2013

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: 16 December, 2013

Trade Name: VitalitE Acetabular Insert for the CS2™ Acetabular Cup System

Common Name: Vitamin E Cross Linked Polyethylene, Acetabular Insert

Device Classification: Class II

Classification(s): Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis: 21 CFR 888.3358, Product Codes LPH & OQG.

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis: 21 CFR 888.3353, Product Codes LZO & OQI.

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis: 21 CFR 888.3360, Product Code KWL.

Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis: 21 CFR 888.3390, Product Code KWY.

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis: 21 CFR 888.3360, Product Code LWJ.

Hip joint metal/polymer semi-constrained cemented prosthesis: 21 CFR 888.3350, Product Codes JDI & OQH.

Device Description:
The Consensus CS2™ Acetabular Cup System consists of a titanium alloy shell (ASTM F620 or F136) and a polyethylene liner (ASTM F648). The system is compatible with the femoral components of all cleared hip systems manufactured by Consensus Orthopedics, Inc.: Consensus Hip System (CHS), TaperSet Hip System (THS), CS2 Hip System (CS2HS), and UniSyn Hip System (UniSyn). The CS2 Acetabular Cup System can be used with the CoCr, zirconia, or Biolox delta femoral heads currently marketed by Consensus and with 22mm, 28mm, 32mm, and 36mm inner diameters. The liners are available in either neutral or hooded versions and with either standard or lateral offsets. 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

shell comes with or without holes for additional screw fixation. The new acetabular liners will be made from UHMPWE that contains vitamin E (α-tocopherol).

Indications for Use:
The VitalitE Acetabular Insert for the Consensus CS2™ Acetabular Cup System is indicated for use with the CONSENSUS® Hip System, TaperSet Hip System, CS2 Hip System, or UNISYN™ Hip System for the following indications:

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, TaperSet, and CS2 femoral stems are indicated for cementless use only.
HA coated implants are indicated for cementless use only.

Substantial Equivalence:

Technological Characteristics/ Substantial Equivalence:
The new VitalitE Acetabular Insert for the CS2 Acetabular Cup System is identical in design to the cross-linked UHMWPE acetabular insert previously cleared for Consensus in the following 510(k)'s: K021466, K070061, and K100933. The vitamin E poly used in the new Consensus CS2 insert is identical to the poly cleared for the StelKast EXp acetabular liner in K094035 and K122773 (with the exception of the radiation dosing level).
Based on the material, characterization data, geometry and mechanical testing, the new VitalitE CS2 Hip is substantially equivalent to legally marketed predicates.

Legally Marketed Devices to which Substantial Equivalence is claimed:
K100933 (Consensus Orthopedics, Inc.): Consensus CS2 Plus Acetabular Inserts (lateralized)
K070061 (Hayes Medical, Inc.): Consensus Hip System 36mm Femoral Head & Acetabular Insert
K021466 (Hayes Medical, Inc.): Cross Linked Polyethylene Acetabular Insert
K122773 (SteKast, Inc.): Cross-Over Acetabular Shell and Liner (lateralized)
K094035 (StelKast, Inc.): EXp Acetabular Shell Liner
K112802 (Pipeline Orthopedics, Inc.): Pipeline Total Hip System

Non-Clinical Performance Data:
Non-clinical testing and analysis were provided, including bench testing, material characterization, and biocompatibility testing. Bench testing of the new stem design included wear testing of the worst case acetabular insert, in addition to disassembly testing which included push-out, lever-out, and torque-out tests.

All of the observed results indicate that the VitalitE Acetabular Insert is substantially equivalent to devices currently marketed. Therefore, the device is as safe, as effective, and performs at least as safely and effectively as legally marketed predicates.

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

December 17, 2013

Consensus Orthopedics, Incorporated
Matthew M. Hull, RAC
Director, Quality Systems & Regulatory Affairs
1115 Windfield Way, Suite 100
El Dorado Hills, California 95762

Re: K130652
Trade/Device Name: VitalitE Acetabular Insert 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: OQG, LPH, LZO, OQI, KWL, KWY, LWJ, JDI, OQH
Dated: November 4, 2013
Received: November 5, 2013

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 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. 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 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,

Ronald P. Jean -S 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): K130652

Device Name: VitalitE Acetabular Insert for the CS2™ Acetabular Cup System

Indications for Use:

The Consensus CS2™ Acetabular Cup System is indicated for use with the CONSENSUS® Hip System, TaperSet Hip System, CS2 Hip System, or UNISYN™ Hip System for the following indications:

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, TaperSet, and CS2 femoral stems are indicated for cementless use only.
HA coated implants are indicated for cementless use only.

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)

Elizabeth L. Frank -S
2013.12.13 16:08:40 -05'00'

Division of Orthopedic Devices