K110542

APR - 1 2011

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
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Date Prepared: 24 February, 2011

Trade Name: Consensus® Hip System, Unisyn Hip System, TaperSet™ Hip System

Common Name: Porous-coated hip prostheses for uncemented use
Non-porous coated hip prostheses for uncemented or cemented use

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis is a Class II device per 21 CFR 888.3358 (Product Code LPH).
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis is a Class II device per 21 CFR 888.3353 (Product Code LZO).

Device Description:
The Consensus hip systems are semi-constrained, hip prosthesis designed for either primary or revision hip surgery. They include the Consensus® Hip System (CHS), the Unisyn™ Hip System, and the TaperSet™ Hip System (THS). All three hip systems utilize the exact same 12/14 Morse taper trunnion. These hip stems are compatible with previously cleared CoCr heads, zirconia heads, unipolar heads, bipolar heads, UHMWPE inserts and acetabular cups.

Indications for Use:
The Consensus hip systems are designed for total or partial hip arthroplasty and are only intended to be used with compatible Consensus components per the appropriate system specific indications.

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.

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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.

Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

Substantial Equivalence:

Technological Characteristics/Substantial Equivalence:
The Consensus hip systems are similar to the predicate Aesculap system in basic design and indications. The predicate Aesculap stems and heads were cleared for use with the Consensus CS2 Acetabular Cup System under K081973. Zirconia ceramic femoral heads were previously cleared with CHS, Unisyn, and THS under various 510(k) submissions. The subject Biolox *delta* ceramic femoral heads were cleared for use with the predicate Aesculap hip systems under K082991. Based on the material, characterization data, geometry and mechanical testing, use of the Biolox *delta* femoral head with the Consensus hip systems is substantially equivalent to legally marketed predicates.

Legally Marketed Devices to which Substantial Equivalence is claimed:
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
K060635 (Hayes Medical, Inc.) Consensus Total Hip System, Acetabular Cup
K021466 (Hayes Medical, Inc.) CONSENSUS ACETABULAR INSERT, CROSS-LINKED POLYETHYLENE
K020153 (Hayes Medical, Inc.) CONSENSUS ACETABLAR SHELL, TI COATED
K953198 (Hayes Medical, Inc.) CORTICELLOUS BONE SCREW
K100933 (Consensus) Consensus Acetabular insert, CS2 Plus
K030151 (Hayes Medical, Inc.) CONSENSUS HIP SYSTEM, UNISYN HIP SYSTEM
K102399 (Consensus) TaperSet Hip System
K081973 (Aesculap) Consensus Acetabular Cups for use with Aescualp Excia and Metha Hip Systems
K082991 (Aesculap) Biolox Delta Ceramic Femoral Head

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Non-Clinical Performance Data:

- All required testing per "Guidance Document for the Preparation of Premarket Notifications of Ceramic Ball Hip Systems" were performed.
- Component testing of BIOLOX *forte* ball head 28-12/14 L on titanium test tapers per CeramTec AG test procedure VA 02 04 4129, ISO 7206-10.
- Influence of diameter and neck length on burst strength of BIOLOX forte and BIOLOX delta ball heads with taper type 12/14. Burst test setup as per ISO 7206-10.

Clinical Performance Data:

No clinical studies were performed..

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

Consensus Orthopedics, Inc.
% Matthew Hull, RAC
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El Dorado Hills, California 95762-9623

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Re: K110542
Trade/Device Name: Consensus Biolox Delta Ceramic Femoral Heads
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: February 22, 2011
Received: February 24, 2011

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 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

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110542

Device Name: BIOLOX® *delta* Ceramic Femoral Heads (w/ Consensus hip systems)

Indications for Use:

The Consensus hip systems are designed for total or partial hip arthroplasty and are only intended to be used with compatible Consensus components per the appropriate system specific indications.

The general 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.

Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

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 M. Melkerson

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

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