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: 14 May, 2012

Trade Name: TaperSet™ Hip System RDP Stems

Common Name: Porous-coated hip prosthesis for cementless use

Classification Name: Class II device
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.
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.

Device Description:
The TaperSet Hip System (THS) is a monolithic, titanium alloy tapered hip stem design with a proximal, plasma sprayed, porous CPTi coating. The stem has a dual wedge geometry and is available in both standard and 7mm lateral offsets in sizes designated as 7.5mm to 24mm. The stems feature a neck shaft angle of 135° and a 12/14 Morse taper trunnion. The TaperSet Hip System is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the Consensus Hip System. The stem is compatible with previously cleared CoCr heads, zirconia or Biolox delta ceramic heads, unipolar heads, bipolar heads, UHMWPE inserts and acetabular cups. The modification addressed here is the addition of a line of stems with a reduced distal profile (RDP) in sizes 10.5mm to 24mm.

Indications for Use:
The TaperSet™ Hip System is 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 TaperSet™ hip stem is indicated for cementless use.

Substantial Equivalence:

Technological Characteristics/Substantial Equivalence:
The new Reduced Distal Profile (RDP) stems for the TaperSet Hip System have the identical neck and taper design, porous coating, and sizing as the predicate TaperSet stems cleared under K102399 in design and indications. A reduced distal profile femoral hip stem design was previously cleared by FDA under K101086 for the Biomet Taperloc Complete Hip System. The subject Consensus RDP stems are still compatible with previously cleared CoCr heads, zirconia and Biolox delta ceramic heads, unipolar heads, bipolar heads, UHMWPE inserts and acetabular cups. Based on the material, characterization data, and geometry, the TaperSet Hip RDP stem is substantially equivalent to the legally marketed predicates.

Non-Clinical Performance Data:

No additional non-clinical testing was performed because there was no proximal design change from the predicate TaperSet and distally the new smallest size is still larger than the smallest predicate TaperSet stem which was previously tested.

Based upon engineering analysis of the design modification the new reduced distal profile stems for the TaperSet Hip System by Consensus are 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Consensus Orthopedics, Incorporated
% Mr. Matthew Hull, RAC
QS & RA Director
1115 Windfield Way, Suite 100
El Dorado Hills, California 95762-9623

MAY 2 2 2012

Re: K121263
Trade/Device Name: TaperSet™ Hip System RDP Stems
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, KWL, KWY
Dated: April 25, 2012
Received: April 26, 2012

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,

for 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): ~~K[illegible]~~ K121263

Device Name: TaperSet™ Hip System RDP Stems

Indications for Use:
The TaperSet™ Hip System is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the Consensus 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.
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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 TaperSet™ hip stem is indicated for cementless use.

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)

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

510(k) Number K121263