K102399

2. 510(k) SUMMARY

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

DEC 2 2010

510(k) Contact: Matthew M. Hull, RAC
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Date Prepared: 29 November, 2010

Trade Name: TaperSet™ Hip System

Common Name: Porous-coated hip prosthesis for cementless 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).

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 heads, unipolar heads, bipolar heads, UHMWPE inserts and acetabular cups.

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 TaperSet Hip System is similar to the predicate systems in basic design and indications. The monolithic stem with porous CPTi coating is considered to have the same type of technological characteristics as the Biomet K043537 stem with differences in the stem geometry and exterior coating. The subject stem is compatible with previously cleared CoCr heads, zirconia heads, unipolar heads, bipolar heads, UHMWPE inserts and acetabular cups. Based on the material, characterization data, geometry and mechanical testing, the TaperSet Hip is substantially equivalent to legally marketed predicates.

Legally Marketed Devices to which Substantial Equivalence is claimed:
K043537 (Biomet) Taperloc® 12/14 Taper Femoral components
K921301 (Biomet) TAPERLOC FEMORAL STEM AND UNIVERSAL ACETABULAR COM
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
K922560 (U.S. Medical Products) CONSENSUS(TM) BIPOLAR 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
K030205 (Hayes Medical, Inc.) CONSENSUS UNIPOLAR HEAD, COCR
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

Non-Clinical Performance Data:

Non-clinical testing and analysis were provided, including bench testing and coating characterization. Bench testing included distal fatigue testing and proximal fatigue testing of the worst case stem consistent with the "Guidance for Industry and FDA Staff Non-clinical Information for Femoral Stem Prostheses." Range of motion analysis was also performed. The CPTi plasma sprayed titanium coating underwent characterization per FDA's "Guidance Document For Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement" and "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements." The CPTi plasma sprayed coating characterization meets the definition of porosity per 21 CFR

888.3358. Modular connection analyses including fretting and corrosion of metallic femoral heads in addition to ceramic head compatibility were also performed.

All of the observed results indicate that the TaperSet Hip System 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 Room –WO66-G609
Silver Spring, MD 20993-0002

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

DEC 2 2010

Re: K102399
Trade/Device Name: TaperSet™ Hip 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, KWL, KWY
Dated: November 10, 2010
Received: November 10, 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

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: K102399

Device Name: TaperSet™ Hip System

Indications for Use:

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The TaperSet™ hip stem is indicated for cementless use.

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)

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

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