DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 4, 2015

Consensus Orthopedics, Incorporated
Mr. Matthew M. Hull
Senior Director, QS & RA
1115 Windfield Way, Suite 100
El Dorado Hills, California 95762

Re: K143725
Trade/Device Name: Consensus Knee System Modular Tibial Baseplate
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY
Dated: January 6, 2015
Received: January 7, 2015

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" (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 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 -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): K143725

Device Name: Consensus Knee System Modular Tibial Baseplate

Indications for Use:

The CONSENSUS® KNEE SYSTEM Primary Knee is designed as a system and is not intended for substitution of components from other systems.

The indications for use are:

A. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
B. Failed osteotomy or unicompartmental replacements.
C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
D. The non-porous (uncoated and coated with CoCr beads without Titanium) components may only be used with cement.
E. The porous coated (CoCr beads with Titanium) components may be used with or without cement.

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)

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: 23 December 2014

Trade Name: Consensus Knee System Modular Tibial Baseplate

Common Name: Modular Tibial Baseplate

Classification Name: Knee joint patellofemorotibial Polymer/metal/polymer semi-constrained cemented prosthesis is a Class 2 device per 21 CFR 888.3560 (Product Code JWH/OIY)

Device Description:
The Consensus Knee System (CKS) modular tibial baseplate is a non-porous (uncoated), anatomic, fixed-bearing design made from cast CoCrMo (ASTM F75). Its boss-and-fin type keel employs a modular 12/14 female taper for assembly with Consensus Revision Knee System (RKS) stems or the RKS taper plug. The CKS modular baseplate is offered in pegged, pegless, and holed configurations. Holed configurations are supplied with preassembled cement dams manufactured from UHMWPE (ASTM F648). All configurations are supplied with a distal plug intended for assembly in the operating room when stems are not desired. Distal plugs are manufactured from UHMWPE (ASTM F648). Other components compatible with the CKS modular baseplate include all CKS tibial inserts, femoral components, and patella components; all RKS femoral components; and the 6.5mm cancellous bone screw used with CKS holed baseplates.

Indications for Use:
The CONSENSUS® KNEE SYSTEM Primary Knee is designed as a system and is not intended for substitution of components from other systems.

The indications for use are:

A. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
B. Failed osteotomy or unicompartmental replacements.
C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
D. The non-porous (uncoated and coated with CoCr beads without Titanium) components may only be used with cement.
E. The porous coated (CoCr beads with Titanium) components may be used with or without cement.

Substantial Equivalence:
Technological Characteristics/ Substantial Equivalence:
The CKS modular baseplate is substantially equivalent to the CKS uncoated CoCr baseplate (K945589, K001456; K110950), the Consensus RKS CoCr baseplate (K100542), and the Natural-Knee II cemented modular baseplate (K023528) regarding its indications for use, technology, and performance. The distal plug used with the CKS modular baseplate, is substantially equivalent to the taper plug used with the NexGen stemmed tibial baseplate (K933785). As with the CKS modular baseplate, all predicate baseplate components are intended for cemented use.

Non-Clinical Performance Data:
Bench testing was carried out on the CKS modular baseplate and distal plug to verify their safety and effectiveness for clinical use. The baseplate tray region was tested per ASTM F1800-12 to ensure the tray would not fail under fatigue when fully supported by its lateral compartment. The keel and its taper connection were tested per ASTM F1800-12 to verify that the keel would not fail under fatigue when fully supported by an intramedullary stem. The distal plug was tested to ensure that it would resist involuntary dislocation from the keel and to ensure that it could be manually inserted and extracted in the operating room using available instrumentation.