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

August 9, 2017

Consensus Orthopedics, Inc.
Zac Johnson
Regulatory Affairs Project Manager
1115 Windfield Way
El Dorado Hills, California 95762

Re: K163167
Trade/Device Name: CKS Plus Knee System
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: July 10, 2017
Received: July 10, 2017

Dear Zac Johnson:

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" (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 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163167

Device Name
CKS Plus Knee System

Indications for Use *(Describe)*
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.
F. Stemmed baseplates of the CKS Plus Knee System are intended for cemented use only

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510(k) SUMMARY

Sponsor Name: Consensus Orthopedics, Inc.
1115 Windfield Way
El Dorado Hills, Ca 95762

510(k) Contact: Name: Zac Johnson
Phone: (916) 355-7154
Fax: (916) 355-7190
Email: zjohnson@consensusortho.com

Date Prepared: 30 July 2017

Trade Name: CKS Plus Knee System

Common Names Total Knee Implant

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

Device Description:
The CKS Plus extension to the Consensus Knee System (CKS) is a primary fixed bearing total knee system offering flexibility to restore knee function using either cruciate retaining (CR) or posterior stabilizing (PS) components with the option of tibial cancellous screw, tibial intramedullary (IM) stem fixation, and tibial augments

Indications for Use:
The CKS Plus Knee System is designed to be used in conjunction with Consensus Knee System Components 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.

F. Stemmed baseplates of the CKS Plus Knee System are intended for cemented use only

Substantial Equivalence:
Consensus Orthopedics, Inc. (COI) asserts the CKS Plus Knee System, an extension to the Consensus Knee System (CKS) implant components to be substantially equivalent to legally marketed predicate devices regarding their indications for use, technology, and performance (Table 6.1). The Primary Predicate used the evaluation of the CKS Plus Knee System is K932837. The CKS Plus Knee System Congruent tibial insert is substantially equivalent to the CKS congruent tibial insert made from standard UHMWPE (K932837, K110950) or VitalitE (K133919). The CKS Fortified Dovetail PS tibial insert is substantially equivalent to the CKS PS tibial insert made from standard UHMWPE (K954818, K110950, K133919). The CKS Plus Knee System PS and PS-C tibial inserts are substantially equivalent to the CKS PS tibial insert made from standard UHMWPE (K954818, K110950) and the Vitamin E material used in the CKS tibial inserts made from VitalitE (K133919). The CKS Plus PCL Substituting tibial inserts are substantially equivalent to the CKS PCL Substituting tibial insert made from conventional UHMWPE (K953443, K110950) and VitalitE (K133919).

The CKS Plus cruciform tibial baseplate is substantially equivalent to the CKS tibial baseplate (K932837, K110950), the CKS uncoated CoCr baseplate (K945589, K001456, K110950), and the Consensus Revision Knee System (CRKS) baseplate (K100542). The CKS Plus Knee System stemmed tibial baseplate is substantially equivalent to the CKS tibial baseplate (K932837, K110950), the CKS uncoated CoCr baseplate (K945589, K001456, K110950), and the Consensus Revision Knee System (CRKS) baseplate (K100542). The CKS Plus tibial augments and screws are substantially equivalent to the CRKS tibial augments and screws (K100542).

All implant devices compatible with the CKS Plus Knee System extension to the Consensus Knee System are legally marketed in the US (Table 6.2). The CKS CR and RLP CR femoral components and the CRKS femoral components intended for use with the CKS Plus Knee System Congruent and PCL Substituting tibial inserts were previously cleared for use with the CKS Congruent and PCL Substituting tibial inserts (K932837, K110950, K133919, K100542). The CRKS femoral component intended for use with the CKS Plus Knee System Congruent and PCL Substituting Tibial inserts was previously cleared for use with the CKS Congruent and PCL Substituting Tibial Inserts (K100542). The CKS PS and RLP femoral components intended for use with the CKS Plus Knee System PS and PS-C tibial, as well as the CKS Fortified Dovetail PS inserts, were previously cleared for use with the CKS PS tibial insert (K954818, K110950).

The CRKS stem and CRKS taper plug intended for use with the CKS Plus Knee System stemmed baseplates were previously cleared for use with the CKS modular baseplate (K143725) and the CRKS baseplate (K100542). The 6.5mm cancellous bone screw intended for use with the CKS Plus Knee System cruciform baseplates was previously cleared for use with the CKS modular baseplate (K143725) and the CKS uncoated CoCr baseplate (K945589). The cement dam intended for use with the CKS Plus Knee System cruciform holed baseplates was previously cleared for use with the CKS modular baseplate (K143725) and the CKS uncoated CoCr

baseplate (K945589). The augment screws intended for use with the CKS Plus 6mm tibial baseplates were previously cleared for use with the CRKS baseplate (K100542). The half wrap versions of all CKS Plus Knee System tibial baseplates are intended for use with previously cleared CKS tibial inserts (K932837, K110950, K133919, K100542).

CKS Fortified Dovetail PS and all CKS Plus Knee System Congruent, PCL Substituting, and PS tibial inserts are intended to be compatible with previously cleared CKS tibial baseplates (K932837, K945589, K001456, K110950), CKS modular baseplates (K143725) and CRKS baseplates (K945589, K100542)

Non-Clinical Performance Data:
Bench testing was carried out on CKS Plus Knee System implant components 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 one compartment collapses. Tibiofemoral joint stability was tested for the PS-C insert per ASTM F1223-14. The tibial insert locking mechanism was tested per FDA's Class II Special Controls Guidance to ensure adequate connection strength and ease of insertion. Wear testing and contact pressure were not deemed necessary because the articular surfaces are identical to the predicate devices. Testing of modular junctions with all previously cleared components (i.e. IM stem, augments) was similarly not tested due to consistency of design. Pyrogenicity testing has been performed.

Testing Performed
Peel Out Testing of the Posterior Stabilized Insert : Verification of a Fortified Dovetail, Report

PS Post Fatigue Testing, Report

Baseplate Fatigue Testing, Report

Tibial Insert Dislocation Testing, Report

1223 Stability Testing, Report

VitalitE PS Post Fatigue Testing, Report

Report_CKS_Wear Sim_Tibiofem_Part Anal_VitE_Congr-RLP_Accutek_K12106826-4_101813

Tray Fatigue: FEA Worst Case Scenario, Report

Stem Fatigue: FEA Worst Case Scenario, Report

Insert Layout Analysis, Report

Range of Motion Analysis, Report

Range of Motion Analysis, Varus/Valgus Tilt,, Report

Tibial Insert Articular Surface Study, Rport

Range of Motion Analysis - Additional Sizes, Report