Consensus Orthopedics, Inc.                                          August 9, 2017
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
Indications for Use

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 CRKS 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 CRKS Plus Knee System Congruent and PCL Substituting Tibial inserts was previously cleared for use with the CRKS 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, Report
Range of Motion Analysis - Additional Sizes, Report