DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 19, 2016

Consensus Orthopedics, Inc.
Zac Johnson
Regulatory Affairs Manager
1115 Windfield Way, Ste 100
El Dorado Hills, California 95762

Re: K160515
Trade/Device Name: PS2 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: November 11, 2016
Received: November 14, 2016

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 yours,

Mark N. Melkerson -S

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 know): K160515

Device Name: PS2 Knee System

INDICATIONS AND USAGE:

The PS2 KNEE SYSTEM 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 PS2 KNEE SYSTEM is intended for cemented 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)

2. 510(k) SUMMARY

Sponsor Name: Consensus Orthopedics, Inc.
1115 Windfield Way, Suite 100
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: 19 February 2016

Trade Name: PS2 Knee System

Common Name: PS2 Total Knee System

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 PS2 Knee System 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 and tibial stem fixation. The uncoated femoral components (CR and PS) and uncoated tibial baseplates (pegged, pegless, and holed) are made from cast CoCr alloy (ASTM F75), and are intended for cemented use only. The tibial inserts (CR and PS) and all-poly patellar components (oval and round) are made from UHMWPE (ASTM F648) or VitalitE (ASTM F2695). The PS2 tibial baseplate employs a modular keel, which is compatible with the previously cleared Consensus Revision Knee System (CRKS) stem and taper plug made from Titanium alloy (ASTM F1472). The PS2 holed baseplate is compatible with the previously cleared Consensus Knee System (CKS) 6.5mm cancellous bone screw made from Titanium alloy (ASTM F136). The PS2 baseplate is supplied with four preassembled cement dams made from UHMWPE and supplied with a distal plug made from UHMWPE intended for assembly in the operating room when stems are not desired.

Indications for Use:
The PS2 KNEE SYSTEM 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 PS2 KNEE SYSTEM is intended for cemented use.

Substantial Equivalence:
Technological Characteristics/ Substantial Equivalence:
Consensus Orthopedics, Inc. (COI) asserts the PS2 implant components to be substantially equivalent to legally marketed predicate devices regarding their indications for use, technology, and performance (Table 6.1). The PS2 cruciate retaining (CR) femoral component is substantially equivalent to the Consensus Knee System (CKS) Reduced Lateral Profile (RLP) uncoated CR femoral component (K110950). The PS2 posterior stabilized (PS) femoral component is substantially equivalent to the CKS RLP uncoated PS femoral component (K110950). The PS2 CR tibial insert is substantially equivalent to the CKS congruent tibial insert made from standard UHMWPE (K932837, K110950) or VitalitE (K133919). The PS2 PS tibial insert is substantially equivalent to the CKS PS tibial insert made from standard UHMWPE (K954818, K110950). The 25mm PS2 tibial inserts are substantially equivalent to the 25mm Genesis II PS tibial insert (Smith & Nephew, K951987). The 30mm PS2 tibial inserts are substantially equivalent to the 30mm Genesis II PS constrained tibial insert (Smith & Nephew, K962137). The PS2 baseplate is substantially equivalent to the CKS modular baseplate (K143725), the CKS uncoated CoCr baseplate (K945589, K001456, K110950), and the Consensus Revision Knee System (CRKS) baseplate (K100542). The PS2 oval and round patellar components are substantially equivalent to the CKS oval and round all-poly patellar components made from standard UHMWPE (K932837) or VitalitE (K133919). As with the PS2 femoral components, tibial baseplate, and patella components; the corresponding predicate devices are intended for cemented use.

All implant devices compatible with the PS2 Knee System are legally marketed in the US (Table 6.2). The distal plug intended for use with the PS2 baseplate was previously cleared for use with the CKS modular baseplate (K143725). The CRKS stem and CRKS taper plug intended for use with the PS2 baseplate 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 PS2 baseplate 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 PS2 holed baseplate was previously cleared for use with the CKS modular baseplate (K143725) and the CKS uncoated CoCr baseplate (K945589).

Table 6.1: Legally marketed devices for which the PS2 implant components demonstrate substantial equivalence.

Primary Vs Secondary Predicate	**Component Name**	**510(k) Number**	**510(k) Trade Name**	**510(k) holder**	**510(k) Release Date**
Primary	CKS RLP uncoated CR femoral component; CKS RLP uncoated PS femoral component; CKS congruent CR tibial insert (20, 22mm); CKS PS tibial insert (20, 22mm); CKS uncoated CoCr baseplate (size 0)	K110950	Consensus® Knee System, Line Extensions; Total knee prosthesis for cemented or uncemented use	COI	6/27/2011
Secondary	CKS congruent CR tibial insert (10-18mm); CKS all-poly patellar component (oval/round)	K932837	Consensus Knee System – Primary Knee	COI	9/27/1994
Secondary	CKS uncoated CoCr baseplate (pegged w/ holes)	K945589	Consensus® Knee Cobalt Chrome Nonporous Stemmed Tibial Baseplate	COI	5/31/1995
Secondary	Genesis II PS tibial insert (9-25mm)	K951987	Genesis II Knee System	S&N	8/22/1995
Secondary	CKS PS tibial insert (10-18mm)	K954818	Consensus Posterior Stabilized Knee	COI	5/22/1996
Secondary	Genesis II PS Constrained tibial insert (9-30mm)	K962137	Genesis II Constrained System	S&N	8/2/1996
Secondary	CKS uncoated CoCr baseplate (pegged w/o holes; pegless w/o holes)	K001456	Consensus® Knee System; Tibial Baseplate, Cast, CoCr/Ti Porous and CoCr Non-Porous	COI	8/7/2000
Secondary	CRKS baseplate	K100542	Consensus Revision Knee System	COI	6/24/2010
Secondary	CKS congruent CR tibial insert; CKS all-poly patellar component (oval/round)	K133919	VitalitE Tibial Insert & Patellar Components	COI	7/14/2014
Secondary	CKS modular baseplate	K143725	Consensus Knee System Modular Tibial Baseplate	COI	3/4/2015

Table 6.2: Legally marketed devices compatible with the PS2 Knee System.

Component Name	510(k) Number	510(k) Trade Name	510(k) holder	510(k) Release Date
6.5mm cancellous bone screw[1]; Cement dam[2]	K945589	Consensus® Knee Cobalt Chrome Nonporous Stemmed Tibial Baseplate	COI	05/31/1995
CRKS stem; CRKS taper plug	K100542	Consensus Revision Knee System	COI	06/24/2010
Distal plug	K143725	Consensus Knee System Modular Tibial Baseplate	COI	03/04/2015

Notes: (1) Bone screws were originally cleared under K922561 for use with Consensus Hip System acetabular components and later cleared under K945589 for use with the predicate CKS CoCr baseplate; (2) Cement dams were originally cleared under K945589 for use with the predicate CKS CoCr baseplate.

Non-Clinical Performance Data:

Bench testing was carried out on PS2 implant components to verify their safety and effectiveness for clinical use. The femoral component was tested to ensure its backside box profile (tensile side) would not fail under fatigue when loaded in a manor to wedge the femoral component onto the femur. 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 per ASTM F1223-12 (torsion) and -14 (translation). Patellofemoral joint stability was tested per the FDA's Class II Special Controls Guidance. Joint contact characteristics were tested per ASTM F2083-12 and FDA's Class II Special Controls Guidance to ensure adequate tibiofemoral and patellofemoral contact area and contact stresses under physiologic loading. 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 was performed on the PS2 tibiofemoral articulation per ISO 14243-1. PS2 PS post fatigue testing was performed in compliance with FDA's Class II Special Controls Guidance. Testing the modular junctions with all previously cleared components (i.e. IM stem) was deemed unnecessary due to consistency in design.