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

October 5, 2017

Re: K170344
Trade/Device Name: Tahoe Uni Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: September 7, 2017
Received: September 7, 2017

Dear Mr. 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 (DICE) 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 (DICE) 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

1. INDICATIONS FOR USE STATEMENT

510(k) Number: K170344

Device Name: Tahoe Uni Knee System

INDICATIONS AND USAGE:

The Tahoe Uni Knee System (TUKS) is designed as a system and is not intended for substitution of components from other systems. The indications for use are as follows:

Primary medial or lateral compartmental intervention of (1) primary non-inflammatory degenerative disease, including osteoarthritis, traumatic arthritis, or osteonecrosis; (2) post-traumatic degenerative disease; (3) varus or valgus deformities; and (4) damage due to previous surgical intervention when the opposite compartment is preserved and when the anterior cruciate, posterior cruciate, medial collateral, and lateral collateral ligaments are present and functional.

All TUKS implants are single use only, and are intended for implantation only with bone cement.

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: 01 February 2017

Trade Name: Tahoe Uni Knee System

Common Name: Unicompartmental Knee System

Classification Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis; Class II device; 21 CFR 888.3520; Product Code: HSX

Device Description:
The Tahoe Uni Knee System (TUKS) is a primary fixed-bearing, round-on-flat unicompartmental knee system offering flexibility to restore function in the affected medial or lateral tibial compartments. The femoral and tibial components are intended for cemented use only. The femoral component is made from cast CoCr alloy (ASTM F75), whereas the tibial baseplate is made from wrought CoCr alloy (ASTM F1537). The tibial insert is made from UHMWPE (ASTM F648) or Vitamin-E polyethylene (VitalitE, ASTM F2695). The tibial insert is designed to snap into the baseplate via an anterior-posterior locking mechanism.

Indications for Use:
The Tahoe Unicompartmental Knee System (TUKS) is designed as a system and is not intended for substitution of components from other systems. The indications for use are as follows:

Primary medial or lateral compartmental intervention of (1) primary non-inflammatory degenerative disease, including osteoarthritis, traumatic arthritis, or osteonecrosis; (2) post-traumatic degenerative disease; (3) varus or valgus deformities; and (4) damage due to previous surgical intervention when the opposite compartment is preserved and when the anterior cruciate, posterior cruciate, medial collateral, and lateral collateral ligaments are present and functional.

All TUKS implants are single use only, and are intended for implantation only with bone cement.

Substantial Equivalence:

Technological Characteristics/ Substantial Equivalence:
The Tahoe Uni Knee System (TUKS) implant components are substantially equivalent to legally marketed devices regarding their indications, technology, and performance (Table 4.1). The TUKS is substantially equivalent to the following unicompartmental knee systems intended for cemented use:

- Uniglide - Femoral component used with all-poly tibial component (K050764).
- Oxford - Femoral component used with Repicci II (K971938) or Vanguard M Series (K021621, K042093) metal-backed tibial components.
- EPIK - Metal-backed tibial component (K022437; K020741).
- Stride - Metal-backed tibial component (K123380).

Non-Clinical Performance Data:
Bench testing, FEA simulations, and engineering justifications were carried out on TUKS implant components to ensure their safety and effectiveness for clinical use. The femoral component was analyzed via FEA simulation to ensure its backside geometry (tensile side) would not fail when deflecting the posterior facet away from the central peg. The tibial baseplate was fatigue tested in 3-point bending per WK45235 to ensure the tray region would not fail under the absence of bone support on the tibial plateau mid-section. Joint stability testing was deemed unnecessary due to the unconstrained round-on-flat articulation. Joint contact characteristics were tested per ASTM F2083-12 to ensure adequate tibiofemoral contact area and contact pressure distribution under physiologic load. The tibial insert locking mechanism was tested to ensure ease of manual insertion and adequate connection strength. Wear testing was deemed unnecessary due to meeting the minimum requirement for poly thickness in the load bearing region (6mm) per ISO 21536. Pyrogenicity testing was completed and was deemed to be within 20 Endotoxin Units per surgical construct per the FDA Guidance Document *Pyrogen and Endotoxins Testing.*