MAR 1 3 2014

510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
Address:	No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan
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Date of Summary:	August 16, 2013
Contact Person	Fang-Yuan Ho Regulation and Document Management
Proprietary Name:	Ultracongruent Insert
Common Name:	Semi-constrained total knee prostheses
Device Classification Name and Reference:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560. This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	JWH
Predicate Device:	1. "United" U2 Total Knee System (K051640) 2. "United" U2 XPE Total Knee System (K103733) 3. "Ortho Development" Balanced Knee System (K090705) 4. "Biomet" Vanguard^{Tm} Complete Knee System (K050222)

Device Description:

The Ultracongruent Insert is designed for the replacement of the bearing and/or articulating surfaces of the proximal tibia composed of an articulating bearing surface fixed in a metal tibial baseplate, and is used for patients with PCL incomplete, absent, nonfunctional or required release. It is used with the cruciate retained (CR) type Femoral Component. The anterior lip of Ultracongruent Insert is more prominent when comparing with the U2 CR Insert (K051640, K103733), which increases the articulating surface area and expands the

circumference to accommodate and stabilize the femur during knee flexion. The Ultracongruent Insert is available in seven proportional sizes (#1~ #7) and five thicknesses (thicknesses of insert + tibial baseplate: 9mm, 11mm, 13mm, 15mm, and 18mm). The minimum thickness of Ultracongruent Insert is 6 mm on the bearing surface. It is manufactured from irradiated UHMWPE which conform to ASTM F2565, while the UHMWPE raw material is in accordance with ASTM F648 and ISO 5834.

Indications:

The U2 Total Knee system is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device system is intended for cemented use only in the U.S.A.

Basis for Substantial Equivalence:

The Ultracongruent Insert has the same indications, size distribution, materials and the same manufacturing and sterilization method as the XPE tibial insert of the "United" U2 Total Knee System. Besides, the basic design, prominent anterior lip height and intended use of the subjected device are similar with the tibial insert of "Ortho Development" Balanced Knee System® (K090705) and "Biomet" Vanguard™ Complete Knee System (K050222).

Performance Data:

Tests as follows were conducted to evaluate the safety and effectiveness of the subjected device, and the test results demonstrated that this device is safe and effective.

a. Constraint Test
b. Contact Area and Contact Pressure
c. Range of Motion
d. Interlocking Strength Test

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

March 13, 2014

United Orthopedic Corporation
Ms. Fang-Yuan Ho
Regulatory Affairs Manager
No. 57, Park Avenue 2, Science Park
Hsinchu, 300
TAIWAN

Re: K132752
Trade/Device Name: Ultracongruent Insert
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
Dated: January 28, 2014
Received: January 29, 2014

Dear Ms. Ho:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Ronald P. Jean -S for

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

Enclosure

Indication for Use

510 (k) Number (if known): K132752

Device Name: Ultracongruent Insert

Indications for Use:

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Prescription Use x AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices