K100981 (1/3)

JUN 14 2010

510(k) Summary of Safety and Effectiveness

Submission Information

Company: United Orthopedic Corporation

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Date Prepared: March 15, 2010

Device Identification

Device Name: Stem, PSA Type

Common Name: Semi-constrained total knee prostheses

Classification Name and Reference : Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis per 21CFR 888.3560. This falls under the Orthopedics panel.

Predicate Device:

1. "UNITED" U2 Total Knee system – PSA Type (K082424)
2. "DEPUY" Anatomic Modular Knee (AMK) System (K864671)
3. "SMITH & NEPHEW" LEGION Revision Knee System (K043440)

Device Description:

"UNITED Stem-PSA Type is an additional size extension of stem to the existing, previously cleared "UNITED" U2 Total Knee system product line (K082424). The

materials, design, safety and effectiveness of this subject are identical to the previously cleared U2 Total Knee system. The only difference from the existing products is the length of stem. This subject stem made of Ti-6Al-4V alloy and will be offered in two types which include straight stem and curved stem. The length of extended straight stem distribute to 150, 200 and 240mm, while the curved stem has 240mm only. Each size of stem has fifteen options in diameter which ranging from 10mm to 24mm. Canal filling stems with spline and flute design provide immediate rigid fixation and resistance to torsional movements. Distal taper is designed to address the problems associated with proximal stress shielding, resulting from distal fixation.

Intended Use

Stem – PSA Type is included in U2 Total Knee System–PSA type. U2 Total Knee System–PSA type is indicated for use in skeletally mature patients with severe knee pain and disability undergoing surgery for knee arthroplasty 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 contraction. This device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue imbalance. U2 Total Knee System–PSA type is designed for cemented use only.

Basis for Substantial Equivalence:

The safety and effectiveness of Stem – PSA Type are substantially equivalent to the legal on-market stem components in the U2 Total Knee System – PSA Type (straight stem: available in length 30, 75, and 100 mm; curved stem: 150, 200 mm), except for its larger length (straight stem: available in length 150, 200, and 240 mm; curved stem: 240mm). The diameters for the stem components in Stem – PSA Type and U2 Total Knee System – PSA Type both range from 10 mm to 24mm. In addition, the subject straight stem is also substantial equivalence to the "DEPUY" Anatomic Modular Knee (AMK) System (K864671), while the curved stem is also substantial equivalence to the "SMITH & NEPHEW" LEGION Revision Knee System (K043440). The materials for the subject and predicate devices are identical.

Performance Data:

The indications for use, materials, design, manufacturing process, sterilization of the Stem – PSA Type are all identical to the legally on-market stem components in the U2 Total Knee System – PSA Type. Besides, locking strength test of Morse Taper, completed as part of the design assurance process demonstrated that this device is safe and effective and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

United Orthopedic Corporation
% Ms. Fang-Yuan Ho
Regulatory Affairs Manager
57 Park Avenue 2, Science Park
Hsinchu
China (Taiwan) 300

JUN 14 2010

Re: K100981
Trade/Device Name: Stem, PSA Type
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: May 14, 2010
Received: May 17, 2010

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

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

Enclosure

Indication for Use

510 (k) Number (if known): K100981

Device Name: Stem, PSA Type

Indications for Use:

Stem – PSA Type is included in U2 Total Knee System–PSA type. U2 Total Knee System–PSA type is indicated for use in skeletally mature patients with severe knee pain and disability undergoing surgery for knee arthroplasty 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 contraction. This device is intended for use in patients who require augmentation and/or stem extensions due to inadequate bone stock and/or require constrained stabilization for tibiofemoral joint due to soft tissue imbalance. U2 Total Knee System–PSA type is designed for cemented use only.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100981