SEP 2 6 2008 K082469

510(k) Summary of Safety and Effectiveness

Submission Information

Company:	United Orthopedic Corporation
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Date Prepared:	August 25, 2008

Device Identification

Device Name:	U2 Patella
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:	"UNITED" U2 Total Knee system, manufactured by United Orthopedic Corporation, K051640, cleared March 01, 2006

Intended Use

The U2 Patella 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 is indicated for cemented use only.

Device Description:

The subject "UNITED" U2 Patella is identical to the legal on-market patellar components in the U2 Total Knee System (available in sizes 26, 29, 32, 35, and 38 mm), except for its larger diameter (available in sizes 41 and 44 mm). The patellar component is machined from extruded UHMWPE bar. It has a three-pegged design for fixation to the host patella and cement groove designed for cemented use only. The radius of dome for the patella components in U2 Patella and U2 Total Knee System are both 23.8 mm. The diameter and length of the pegs of these two systems are 5.0 mm and 4.5 mm, respectively.

Statement of Technological Comparison

The materials for the subject and predicate devices are identical. The design of the subject and predicate device is the same, except that the subject device has larger size: 41 and 44 mm diameter. The performance testing is sufficient to demonstrate that the subject and predicate devices are substantially equivalent with regard to design. The modification does not change the intended use or fundamental scientific technology.

Performance Data:

Performance testing, including patellofemoral contact area and lateral stability testing of the U2 Patella, 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
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

United Orthopedic Corporation
% Mr. Rudy Chen
Regulatory Affairs, Manager
No. 57, Park Avenue 2, Science Park,
Hsinchu 300, Taiwan

Re: K082469
Trade/Device Name: U2 Patella
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Codes: JWH
Dated: August 25, 2008
Received: August 27, 2008

Dear Mr. Chen:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indication for Use

510 (k) Number (if known): K082469

Device Name: U2 Patella

Indications for Use:

This device 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 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 General, Restorative, and Neurological Devices

510(k) Number K082469