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5. 510(k) Summary

DEC - 8 2010

Manufacturer: U & I Corporation
529-1, Yonghyun-dong, Uijungbu
Kyunggi-Do, Korea 480-050
Gyeong-Je Kwon, Regulatory Affairs Specialist

Sponsor: U & I Corporation
529-1, Yonghyun-dong, Uijungbu
Kyunggi-Do, Korea 480-050

Sponsor Contact: Gyeong-Je Kwon, Regulatory Affairs Specialist

Date Prepared: August 19, 2010

Trade Name: *OptiGen™ Total Knee System*

Common Name: Total Knee System

Classification Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, per 21 CFR 888.3560

Product Code: JWH

Predicate Devices: Genesis II Total Knee System - K951987
Maxim Knee System - K915132, K922285, K993159
P.F.C Sigma Knee System - K884796, K892394, K935262
NexGen CR-Flex, LPS-Flex System – K933785, K023211
U2 Total Knee System – K021657
MG II Porous Total Knee System – K892800

Description of Device:

OptiGen™ Total Knee System consists of femoral components(PS, CR), tibial components, tibial bearings(PS, CR), patellar components and accessories(locking bars, tibial cement plug). Components are available in a variety of designs and size ranges intended for primary application with bone cement. Implant components are made from materials meeting the requirements of various widely recognized standards including ISO, ASTM.

Materials

Femoral components	CoCrMo Alloy (ASTM F75)
Tibial Components	Titanium Alloy (ASTM F136)
Tibial Bearings	UHMWPE (ASTM F648)
Patellar Components	UHMWPE (ASTM F648)
Tibial Cement Plug	UHMWPE (ASTM F648)
Locking Bars	Titanium Alloy (ASTM F136)

Intended Use:

The *OptiGen™ Total Knee System* is indicated for patients with severe knee pain and disability due to:

- Rheumatoid arthritis
- Post-traumatic arthritis, osteoarthritis, or degenerative arthritis
- Failed osteotomies, unicompartmental replacement, or total knee replacement
- Moderate varus, valgus, or flexion deformities

This device is indicated for cemented use only.

Substantial Equivalence:

The *OptiGen™ Total Knee System* is substantially equivalent to Genesis II Total Knee System(K951987), Maxim Knee System(K915132, K922285, K993159), P.F.C Sigma Knee System(K884796, K892394, K935262), NexGen CR-Flex, LPS-Flex System(K933785, K023211), U2(K021657), MG II(K892800) in design, performance, function and intended use.

1. Comparison technological characteristics

The Predicate and proposed devices have the similar intended use and basic fundamental scientific technology and share the following similarities:

- The similar indications for use
- Similar design features
- Incorporate the same or similar materials
- The equivalent mechanical performance

2. Performance Testing

The *OptiGen™ Total Knee System* was tested in a non clinical setting (bench testing) to assess that no new safety and efficiency issues were raised with this device. The testing met all acceptance criteria and verifies that performance of the *OptiGen™ Total Knee System* is substantially equivalent to the predicate devices.

The following tests were performed:
(1) Static test
- A/P shear test
- M/L shear test
- Tensile pull-off test
- Locking bar removal test
- A/P draw test
- M/L draw test
- I/E roration test
- Patellofemoral subluxation test
- Tibial tray test
- Post shear test
- Femorotibial contact test
- Patellofemoral contact test

(2) Dynamic test
- Tibial tray test
- Post shear test

3. Conclusion

The data and information provided in this submission support the conclusion that the *OptiGen™ Total Knee System* is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.

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

U&I Corporation
% Mr. Gyeong-Je Kwon
Assistant Manager, Regulatory Affairs
529-1, Yonghyun-dong, Uijungbu
Kyunggi-Do, Korea 480-050

DEC - 8 2010

Re: K102367
Trade/Device Name: OptiGen™ Total 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
Dated: November 19, 2010
Received: November 22, 2010

Dear Mr. Kwon:

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

K102367

Indications for Use Statement

DEC - 8 2010

510(k) Number (if known): K102367

Device Name: *OptiGen™ Total Knee System*

Indications for Use:

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- Rheumatoid arthritis
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- Moderate varus, valgus, or flexion deformities

This device is indicated for cemented use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

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

510(k) Number K102367