K121974 (1/4)

SEP 6 2012

5.0 510(K) SUMMARY (page 1 of 4)

Submitter's Name and Address	ConforMIS Inc. 11 North Ave. Burlington, MA 01803
Establishment Registration Number	3004153240 and 3008690421
Date of Summary	July 03, 2012
Contact Person	Amita S. Shah, Vice President, Quality Assurance and Regulatory Affairs
Telephone Number	(781) 345-9164
Fax Number	(781) 345-0104
Name of the Device	ConforMIS iUni Unicondylar Knee Replacement System
Common or Usual Name	Unicondylar Knee Replacement System
Classification Name	• Prosthesis, knee, femorotibial, non-constrained, cemented, metal/polymer • Knee Arthroplasty Implantation System
Regulation Number	21 CFR 888.3520
Device Classification	Product Code: • HSX - Knee joint femorotibial metal/polymer non-constrained cemented prosthesis • OOG - Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Intended to be used to assist in the implantation of a specific knee arthroplasty device or a set of specific knee arthroplasty devices. Indicated to include guiding alignment, making or establishing cuts, selecting, sizing, attaching, positioning or orienting implant components.

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Indications for Use

Indications for Use:

The ConforMIS Unicondylar Knee Replacement System (iUni) is intended for use in one compartment of the osteoarthritic knee to replace the damaged area of the articular surface in patients with evidence of adequate healthy bone sufficient for support of the implanted components.

Candidates for unicondylar knee replacement include those with:

- joint impairment due to osteoarthritis or traumatic arthritis of the knee,
- previous femoral condyle or tibial plateau fracture, creating loss of function,
- valgus or varus deformity of the knee,
- revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

This implant is intended for cemented use only.

Identification of the Legally Marketed Device (Predicate Device)

ConforMIS iUni Unicondylar Knee Replacement System
Device Class: II
Product Code: HSX, OOG
Regulation Number: 21 CFR 888.3520
510(k) number: K111916, K092441, K072586, K072368, K063432, K043570

Smith & Nephew Journey Unicondylar
Device Class: II
Product Code: HSX
Regulation Number: 21 CFR 888.3520
510(k) number: K102069

Zimmer Unicompartmental Knee System
Device Class: II
Product Code: HSX
Regulation Number: 21 CFR 888.3520
510(k) number: K033363

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Device Description

ConforMIS iUni Unicondylar Knee Replacement System ("iUni KRS") is a patient-specific unicompartmental knee replacement system. The iUni is comprised of a set of implants designed from patient images. The implant system consist of:

- 1 Femoral Implant
- 1 Tibial Component (all-polyethylene or metal backed)

The implants of the iUni KRS will be composed of individually packaged femoral and tibial components and will be provided with ancillary instrumentation to assist in the implantation procedure.

The patient-specific femoral implant will be made of Cobalt Chrome Molybdenum alloy (CoCrMo) and will be personalized to match a patient's anatomy.

The all poly tibial component is made from UHMWPE. The metal backed tibial component will consist of a CoCrMo tibial tray and with an Ultra High Molecular Weight Polyethylene (UHMWPE) tibial insert. Multiple inserts of varying thicknesses may be provided to accommodate surgeon preferences.

The outline bone contacting and articular surfaces of the femoral component as well as the outline of both tibial components are personalized to match the patient's femoral and tibial anatomy. The design of the implant is derived from an analysis, using proprietary software, of images obtained by MRI or CT scan.

Disposable, patient-specific instrumentation is provided to assist in the implantation of the iUni Unicondylar Knee Replacement System.

Substantial Equivalence:

The product subject of this premarket notification is substantially equivalent to the iUni Unicondylar Knee Replacement System (K111916 cleared September 29, 2011, K092441 cleared September 09, 2009, K072586 cleared November 08, 2007, K072368 cleared September 20, 2007, K063432 cleared March 16, 2007, and K043570 cleared March 14, 2005); Smith & Nephew Journey Unicondylar (K102069 cleared October 05, 2010); and Zimmer Unicompartmental Knee System (K033363 cleared January 16, 2004).

The purpose of this submission is to clarify the indications for use statement and make it consistent with predicate devices and FDA guidance.

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Description and Conclusion of Testing	The determination of substantial equivalence for this device was based on the indications for use statements and the device design. The design of the iUni KRS was previously determined to be substantially equivalent to predicate devices. A comparison of the designs and the indications for use statements confirmed that the modification to the indications for use does not affect device performance and is, therefore, also substantially equivalent.
Safety and Performance	The determination of substantial equivalence for this device was based on detailed device description and indications for use statement comparisons. Non-clinical laboratory testing was not performed as there is no change to the device. Clinical data is not necessary to demonstrate substantial equivalence.
Conclusion	Based on device description and indications for use statement comparisons, it is concluded that the ConforMIS iUni Unicondylar Knee Replacement System with the updated indications for use statement is substantially equivalent to the iUni Unicondylar Knee Replacement System (K111916 cleared September 29, 2011, K092441 cleared September 09, 2009, K072586 cleared November 08, 2007, K072368 cleared September 20, 2007, K063432 cleared March 16, 2007, and K043570 cleared March 14, 2005); Smith & Nephew Journey Unicondylar (K102069 cleared October 05, 2010); and Zimmer Unicompartmental Knee System (K033363 cleared January 16, 2004)

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

Conformis, Incorporated
% Ms. Amita S. Shah
Vice President, Quality Assurance and Regulatory Affairs
11 North Ave
Burlington, Massachusetts 01803

SEP 6 2012

Re: K121974
Trade/Device Name: ConforMIS® Unicondylar Knee Replacement System (iUni)
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: July 3, 2012
Received: July 9, 2012

Dear Ms. Shah:

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 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

Indications for Use

510(k) Number (if known): K121974

Device Name:
ConforMIS® Unicondylar Knee Replacement System (iUni)

Indications for Use:
The ConforMIS Unicondylar Knee Replacement System (iUni) is intended for use in one compartment of the osteoarthritic knee to replace the damaged area of the articular surface in patients with evidence of adequate healthy bone sufficient for support of the implanted components.

Candidates for unicondylar knee replacement include those with:

- joint impairment due to osteoarthritis or traumatic arthritis of the knee,
- previous femoral condyle or tibial plateau fracture, creating loss of function,
- valgus or varus deformity of the knee,
- revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

This implant is intended 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)

Mark Ryde for mXm

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

510(k) Number K121974