K111916 (1/2)

SEP 29 2011

7.0 510(k) SUMMARY

This 510(k) Summary for the ConforMIS® iUni Unicondylar Knee Replacement System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name and Address:	ConforMIS Inc. 11 North Ave. Burlington, MA 01804
Contact Person:	Amita S. Shah Vice President, Quality and Regulatory Affairs
Date:	July 1, 2011
Name of Medical Device:	Device Regulation: 21 CFR 888.3520, 21CFR 888.3560 Product Code: HSX, Knee joint femorotibial metal/polymer non-constrained cemented prosthesis. OOG, Knee joint patellofemerotibial polymer/metal/polymer semi-constrained cemented prosthesis. Common/Usual Name: Unicondylar Knee Replacement System Proprietary Name: ConforMIS iUni Unicondylar Knee Replacement System (iUni KRS)
Device Classification:	In accordance with 21 CFR 888.3520, a knee joint femorotibial metal/polymer non-constrained cemented prosthesis is classified by the FDA as a Class II Medical Device.
Indications for Use:	The ConforMIS Unicondylar Knee Replacement System (iUni KRS) with curved tibial insert 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 repair 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 and • valgus or varus deformity of the knee. **This implant is intended for cemented use only.**

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Device Description:

The ConforMIS iUni Implant System is comprised of a set of implants designed from patient images. The implants consist of

- 1 Femoral Implant
- 1 Tibial Tray
- 2 or 3 Tibial Inserts

The implants of the iUni Implant System will be composed of individually packaged femoral and tibial components.

The femoral implant will be made of Cobalt Chrome Molydenum (CoCrMo) and will be personalized to match a patient's anatomy, thus becoming patient specific.

The tibial implants will consist of a CoCrMo tibial tray and two or three Ultra High Molecular Weight Polyethylene (UHMWPE) tibial inserts of varying thicknesses.

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 currently marketed iUni Unicondylar Knee Repair System (reference K043570, K063432, K072368, K072586 and K092441) and other currently marketed; cemented unicondylar knee replacement systems. The following testing was performed to establish substantial equivalence:

- Femoral Fatigue
- Femoral Implant fixation
- Cadaveric testing
- Software validation testing to support changes to the iUni KRS

Safety and Performance:

The determination of substantial equivalence for this device was based on a detailed device description. Non-clinical laboratory testing was performed demonstrating that the device is safe and can be considered substantially equivalent to the predicate device for the proposed intended use. Clinical data is not necessary to demonstrate substantial equivalence.

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, Inc.
% Ms. Amita Shah
Vice President, Quality Assurance and Regulatory Affairs
11 North Avenue
Burlington, Massachusetts 01803

SEP 29 2011

Re: K111916
Trade/Device Name: ConforMIS® iUni Unicondylar Knee Replacement System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX, OOG
Dated: July 1, 2011
Received: July 6, 2011

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.

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,

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

Enclosure

K111916

6.0 INDICATION FOR USE STATEMENT

510(k) Number (if known): K111916

Device Name: ConforMIS® iUni Unicondylar Knee Replacement System

Indications for Use:
The ConforMIS Unicondylar Knee Replacement System (iUni KRS) with curved tibial insert 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 repair 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 and
- valgus or varus deformity of the knee.

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 IF NEEDED)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K111916