K072586 # 1/3

Summary of Safety and Effectiveness

NOV 0 8 2007

Submitted By: ConforMIS, Inc.
2 Fourth Avenue
Burlington, MA 01803

Contact Person: S. Michael Sharp, PhD
Sr. VP, Regulatory and Clinical Affairs
Phone 781.860.5111
FAX 781.860.5108

Date: September 14, 2007

Trade/Proprietary Name Unicondylar Knee Repair System/
ConforMIS™ UCD

Common Name Unicondylar Knee System

Reference/Classification Name 21 CFR 888.3520 – Knee joint femorotibial metal/polymer non-constrained cemented prosthesis

Predicate Devices:

Technological Characteristics	Indications for Use
• ConforMIS Bicompartmental Knee (K053488) • ConforMIS Total Knee (K0526876)	• ConforMIS Unicondylar Knee (K 043570

Intended Use: The ConforMIS Unicondylar Knee System is intended for use in patients with:

- joint impairment due to osteoarthritis or traumatic arthritis of the knee
- Previous tibial condyle or plateau fracture, creating loss of function
- valgus or varus deformity of the knee

The ConforMIS Unicondylar Knee System is intended for use with cement.

Use of the Term "Substantial Equivalence"

The term "Substantial Equivalence" is used in this submission within the confines of its statutory use in the FDA's evaluation of a Pre-Market Notification Submission. Any statement regarding Substantial Equivalence used in this submission relates only to whether the device that is the subject of this submission may be lawfully marketed in the United States without pre-market approval or reclassification, and should not be interpreted as an admission, or any kind or type of evidence, in any patent proceeding, including patent infringement litigation or proceeding before any Patent Office.

The present submission and statements therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in the submission, or its use, may be considered indistinct, from a patentability perspective, from any other device referred to in this sub mission.

Device Description	The ConforMIS Unicondylar Knee System ("iUni") is a device developed from patient CT scans or MR images to replace one compartment of the knee condyles. It is unconstrained in the anteroposterior and mediolateral directions and allows internal/external rotation between the femoral and tibial components. Movement is limited by the ligaments and other soft tissues surrounding the device. The device is designed to match the patient's unique normal anatomy.
Comparison to Predicates:	The ConforMIS Unicondylar Knee System ("iUni") designed from MR images is substantially equivalent to the ConforMIS Unicondylar Knee System designed from CT Scan data, in technological characteristics in terms of design method, design characteristics and production process, as well as materials and indications. It is substantially equivalent to the ConforMIS Bi-Condylar Knee System and the ConforMIS total knee system in terms of design method, materials and manufacturing methods. All are intended for cemented use only.
Performance Data	Non-clinical Performance and Conclusions: The design verification procedure for the ConforMIS Unicondylar Knee System ("iUni") found that implants designed using MRI data to have the same physical parameters as those for the same patient designed from CT scan data. As all implants are made of the same materials, using identical manufacturing methods, it was concluded that

	implants designed from MR images would be aas safe and effective as the predicate device, the previously cleared version of the implant designed based on CT scan data.
Clinical Performance:	Clinical data and conclusions are not necessary to demonstrate substantial equivalence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2007

ConforMIS, Inc.
% S. Michael Sharp, Ph.D.
Sr. Vice President, Regulatory and Clinical
2 Fourth Avenue
Burlington, Massachusetts 01803

Re: K072586
Trade/Device Name: ConforMIS Uni-Condylar Knee 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
Dated: September 12, 2007
Received: September 13, 2007

Dear Dr. Sharp:

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.

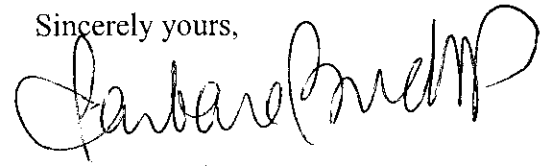
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Indications for Use

510(k) Number (if known): K072586

Device Name: ConforMIS™, Inc. Uni-condylar Knee Repair System

Indications for Use:

The ConforMIS unicondylar implant is intended for use in patients with:

- joint impairment due to osteoarthritis or traumatic arthritis of the knee
- previous tibial condyle or plateau fracture, creating loss of function
- valgus or varus deformity of the knee

The ConforMIS unicondylar implant is for use with bone cement

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(Posted November 13, 2003)

510(k) Number K072586