MAR 9 2006

510(k) Summary

ConforMIS, Inc.

BiCompartmental Knee Repair System

510(k) Premarket Notification K 053488

GENERAL INFORMATION

Manufacturer:

ConforMIS Inc.
323 C Vintage Park Drive
Foster City, CA 94404
Phone 650-286-4151
FAX 650-286-4160

Contact Person:

Patrick Hess, PhD
Chief Executive Officer
ConforMIS, Inc.

Date Prepared: December 5, 2005

DEVICE INFORMATION

Trade/Proprietary Name:
BiCompartmental Knee Repair System

Common/Classification Name:
Knee joint femorotibial cemented prosthesis

Classification: 21 CFR 888.3530 – Knee joint femorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Device Class: Class II

Device Product Code: NPJ

PREDICATE DEVICES

The ConforMIS, Inc. BiCompartmental Knee Repair System is substantially equivalent to FDA-approved predicate devices with regard to indications for use and technological characteristics. These predicate devices are:

Technological Characteristics	Indications for Use
• Imaging Therapeutics™ Knee Interpositional Device (K033242) • ConforMIS Unicondylar Knee (K043570)	• Smith & Nephew Hybrid Knee Femoral Components (K042896) • ConforMIS Unicondylar Knee (K043570) • Natrual Knee® - Sulzer Orthopedics (K002356)

INTENDED USE

The ConforMIS, Inc., BiCompartmental Knee Repair System is intended for use in patients with severe knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only a single knee compartment, such as a unicondylar or patellofemoral prosthesis. The indications for use include restoring joint function and relief of pain due to:

- painful joint disease due to osteoarthritis, traumatic arthritis or rheumatoid arthritis of the knee
- post traumatic loss of joint function
- failed osteotomies, hemiarthoplasties and unicondylar implants.

The BiCompartmental Knee Repair System may be utilized when the medial or lateral condyle and the patellofemoral areas have been affected by one or more of these conditions.

The ConforMIS, Inc., BiCompartmental Knee Repair System is intended only for use with bone cement.

PRODUCT DESCRIPTION

The ConforMIS, Inc., BiCompartmental Knee Repair System is a femorotibial semi-constrained total knee implant. The design of the product incorporates a bone preserving approach, with minimal bone resection, for the treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma. It is intended for use in those patients whose condition cannot be appropriately and effectively addressed using a device that treats only a single knee compartment

(i.e. a unicondylar or patellofemoral prosthesis), when the medial or lateral condyle and the patellofemoral regions are affected. Using patient imaging (either CT or MRI scans), a patient specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The treatment allows for the placement of a cemented metallic device designed from the patient's natural bone geometry. The device is manufactured from cobalt chromium molybdenum alloy (ASTM-F-1537) from data obtained from images of the patient's individual geometry obtained using either CT or MRI scans. The tibial and patellar components are manufactured from Ulta-High Molecular Weight Polyethylene ("UHMWP" ASTM-F-648) The ConforMIS, Inc., Implant Software is used to remove surface defects to produce a working design image of a smooth surface. Off the Shelf (OTS) software is utilized to produce the surface design. Subsequently, Solid Works OTS software is used to create the ConforMIS, Inc., Implant Engineering Drawing. The BiCompartmental Knee Repair System is intended for use in conjunction with the tibial components of the ConforMIS Unicondylar Knee Replacement System and the patellofemoral components of the ConforMIS Total Knee Repair System.

SUBSTANTIAL EQUIVALENCE

Use of the Term "Substantial Equivalence"

The term "Substantial Equivalence" is used in this submission within the confines of the statutory use of the term 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 submission.

Technological Characteristics

The technological characteristics of the ConforMIS, Inc., BiCompartmental Knee Repair System are substantially equivalent to those of the cited predicate orthopedic devices. The image analysis is identical to that used for the Imaging Therapeutics Interpositional Device (iPD) and the ConforMIS Unicondylar Implant. This device is equivalent in terms of design process, materials, production process, and equipment.

Indications for Use

Substantial equivalence is also supported for the ConforMIS, Inc., BiCompartmental Knee Repair System by the predicate devices previously cited and cleared in the treatment of osteoarthritic knees the use of such a device is warranted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 2006

ConforMIS, Inc
c/o Patrick Hess, PhD
Chief Executive Officer
323 Vintage Park Drive, Suite C
Foster City, California 94404

Re: K053488
Trade/Device Name: ConforMIS BiCompartmental Knee Repair System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: NPJ
Dated: December 13, 2006
Received: December 16, 2006

Dear Dr. Hess:

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 Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Retorative
and Neurological Devices
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K _____

Device Name: ConforMIS, Inc., BiCompartmental Knee Repair System

Indications for Use:

The ConforMIS, Inc., BiCompartmental Knee Repair System is intended for use in patients with severe knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only a single knee compartment, such as unicondylar or patellofemoral prosthesis. The indications for use include restoring joint function and relief of pain due to:

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

(PLEASE DO NOT WRITE BELOW THIS LINE-

CONTINUE ON ANOTHER PAGE IF NEEDED)

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

510(k) Number K053488