K093513

6.0 510(k) SUMMARY

This 510(k) Summary for the modified ConforMIS® iDuo Bicompartmental Knee Repair System (iDuo® KRS) is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name and Address:	ConforMIS Inc. 2 Fourth Ave. Burlington, MA 01804 DEC 16 2009
Contact Person:	Amita S. Shah Director, Quality Assurance & Regulatory Affairs
Date:	November 12, 2009
Name of Medical Device:	Device Regulation: 21 CFR 888.3560, Product Code: NPJ Common/Usual Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. Proprietary Name: ConforMIS iDuo Bicompartmental Knee Repair System
Device Classification:	In accordance with per 21 CFR 888.3560, a knee joint patellofemorotibial polymer/metal/polymer non-constrained cemented prosthesis is classified by the FDA as a Class II Medical Device.

Indications for Use:

The ConforMIS iDuo Bicompartmental Knee Repair System (iDuo KRS) 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 including 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, hemiarthroplasties and unicondylar implants

The iDuo KRS may be utilized when the medial or lateral condyle and the patellofemoral areas have been affected by one or more of these conditions. The iDuo KRS is intended for cemented use only.

Device Description:

The **iDuo KRS** is a semi-constrained cemented knee implant which consists of a femoral, tibial and patellar component (patellar component packaged separately). The product design 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 or effectively addressed using a device that treats only a single knee compartment (i.e. a unicompartmental or patellofemoral prosthesis) when the medial or lateral condyle and the patellofemoral regions are affected.

Using patient imaging (either CT or MR scans), a patient-specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The device is manufactured from cobalt chromium molybdenum ("CoCrMo") alloy. Two tibial components are

offered: a single-piece all polyethylene tibial component manufactured from ultra-high molecular weight polyethylene ("UHMWPE") or a two-piece metal-backed tibial component which includes a metal tray manufactured from CoCrMo alloy and a polyethylene insert manufactured from UHMWPE. The patellar component is manufactured from UHMWPE.

Substantial Equivalence:

The product subject of this premarket notification is substantially equivalent to the currently marketed iDuo Bicompartmental Knee Repair System (reference K053488 cleared March 9, 2006) and other currently marketed devices.

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 are not necessary to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Conformis, Inc.
% Ms. Amita Shah, RAC
Director, Quality Assurance & Regulatory Affairs
2 Fourth Ave
Burlington, Massachusetts 01803

DEC 16 2009

Re: K093513
Trade/Device Name: iDuo Bicompartmental Knee Repair 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: NPJ
Dated: November 12, 2009
Received: November 17, 2009

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

5.0 INDICATION FOR USE STATEMENT

510(k) Number (if known):

Device Name: ConforMIS® iDuo® Bicompartmental Knee Repair System (iDuo KRS)

Indications for Use:

The ConforMIS iDuo Bicompartmental Knee Repair System (iDuo KRS) 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 including restoring joint function and relief of pain due to:

- painful joint disease due to osteoarthritis, traumatic arthritis or rheumatoid arthritis of the knee,
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The iDuo KRS may be utilized when the medial or lateral condyle and the patellofemoral areas have been affected by one or more of these conditions.

The iDuo KRS is intended for cemented use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K093513