

6.0 510(K) SUMMARY (PAGE 1 OF 4)

DEC 05 2013

Submitter's Name and Address: ConforMIS Inc.
28 Crosby Drive
Bedford, MA 01730

Establishment Registration Number: 3009844603 and 3004153240

Date of Summary: August 21, 2013

Contact Person: Amita S. Shah, Sr. Vice President, Regulatory and Quality Affairs

Telephone Number: (781) 345-9164
Fax Number: (781) 345-0104

Name of the Device: ConforMIS iUni Unicondylar Knee Replacement System (KRS)

Common Name: Unicondylar Knee Replacement System

Regulatory Status and Regulation Number: Class II
21 CFR 888.3520

Classification Name:

- HSX - Prosthesis, knee, femorotibial, nonconstrained, cemented, metal/polymer
- OOG - Knee Arthroplasty Implantation System

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 (KRS)
Device Class: II
Product Code: HSX, OOG
Regulation Number: 21 CFR 888.3520
510(k) Number: K121974 and K111916

510(K) SUMMARY (PAGE 2 OF 4)

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

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

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

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

The all poly tibial component is made from UHMWPE. The metal backed tibial component consists 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, the bone contacting surfaces, and the 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 (K121974 cleared September 06, 2012 and K111916 cleared September 29, 2011). The following testing was performed to establish substantial equivalence:

- Software verification and validation testing of proprietary software

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Device Comparison

Characteristic	Predicate iUni Unicondylar Knee Replacement System (K121974 & K111916)	iUni Unicondylar Knee Replacement System (This submission)
Indication for Use	<p>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.</p> <p>Candidates for unicondylar knee replacement include those with:</p> <ul style="list-style-type: none"> • 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 • revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans <p>This implant is intended for cemented use only.</p>	<p>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.</p> <p>Candidates for unicondylar knee replacement include those with:</p> <ul style="list-style-type: none"> • 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 <p>This implant is intended for cemented use only.</p>
Cement Use Only	Yes	Yes
Product Classification	21 CFR 888.3520 (HSX)	21 CFR 888.3520 (HSX)
Components and Materials	<ul style="list-style-type: none"> • Femoral Implant: CoCrMo • Metal Backed Tibial Components: <ul style="list-style-type: none"> ○ Tibial tray: CoCrMo ○ Tibial Inserts: UHMWPE • All-Polyethylene Tibial Component: UHMWPE 	<ul style="list-style-type: none"> • Femoral Implant: CoCrMo • Metal Backed Tibial Components: <ul style="list-style-type: none"> ○ Tibial tray: CoCrMo ○ Tibial Inserts: UHMWPE • All-Polyethylene Tibial Component: UHMWPE
Design	Prosthesis, knee, femorotibial, nonconstrained, cemented, metal/polymer	Prosthesis, knee, femorotibial, nonconstrained, cemented, metal/polymer
Patient Matched	Yes	Yes
Instrumentation	Patient-specific Nylon jigs	Patient-specific Nylon jigs

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Characteristic	Predicate iUni Unicondylar Knee Replacement System (K121974 & K111916)	iUni Unicondylar Knee Replacement System (This submission)
Proprietary Software for Segmenting and Surfacing	SegSurf version 2.0	SegSurf version 3.0
Proprietary Software for Femoral Components	iUniWorks version 3.0	iUniWorks version 4.0
Proprietary Software for the Femoral Trial	iUni FemJigs version 1.3	iUni FemJigs version 2.0

Description and Conclusion of Testing:

Nonclinical Testing: The determination of substantial equivalence for this device was based on a detailed device description. The following non-clinical laboratory testing was performed demonstrating that the device is safe and can be considered substantially equivalent to the predicate device for the intended use:

- Detailed software description and software verification and validation testing of proprietary software SegSurf
- Detailed software description and software verification and validation testing of proprietary software iUniWorks
- Detailed software description and software verification and validation testing of proprietary software iUni FemJigs

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 intended use. Clinical data is not necessary to demonstrate substantial equivalence.

Conclusion:

Based on the testing conducted it is concluded that the iUni Unicondylar Knee Replacement System with the use of SegSurf v3.0, iUniWorks v4.0, and iUni FemJigs v2.0 production software modules is substantially equivalent to the iUni Unicondylar Knee Replacement System (K121974 cleared September 06, 2012 and K111916 cleared September 29, 2011).



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

ConforMIS, Incorporated
Ms. Amita Shah
Senior Vice President, Regulatory and Quality Affairs
28 Crosby Drive
Bedford, Massachusetts 01730

December 5, 2013

Re: K132640

Trade/Device Name: ConforMIS[®] iUni 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, OOG

Dated: September 5, 2013

Received: September 9, 2013

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 contact 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>. 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 CDRI'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 -S

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

Enclosure

Indications for Use

510(k) Number (if known): K132640

Device Name:

ConforMIS® iUni 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.

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- 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)

