JAN - 9 2014

6.0 510(K) SUMMARY

Submitter's Name and Address:	ConforMIS Inc. 28 Crosby Drive Bedford, MA 01730
Establishment Registration Number:	3009844603 and 3004153240
Date of Summary:	October 22, 2013
Contact Person:	Amita S. Shah, Sr. Vice President, Regulatory and Quality Affairs
Telephone Number:	(781) 345-9164
Fax Number:	(781) 345-0147
Name of the Device(s):	ConforMIS iTotal CR Knee Replacement System ConforMIS iUni Unicondylar Knee Replacement System ConforMIS iDuo Bicompartmental Knee Repair System
Common Name(s):	Total Knee Replacement System Unicondylar Knee Replacement System Bicompartmental Knee Replacement System
Regulatory Status and Regulation Number:	Class II 21 CFR 888.3560, 21 CFR 888.3520
Device Classification:	Class II Product Codes: JWH, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

OOG, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Intended to be used to assist in the implantation of a specific knee arthroplasty device or a set of specific knee arthroplasty devices. Indicated to include guiding alignment, making or establishing cuts, selecting, sizing, attaching, positioning or orienting implant components.

NPJ, Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

HSX, Knee joint femorotibial metal/polymer non-constrained cemented prosthesis

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Indications for Use: **iTotal**

The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis. The indications for use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.
- 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.

iUni

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.

iDuo

The ConforMIS iDuo 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 :

- Painful joint disease due to osteoarthritis
- Traumatic arthritis of the knee
- Post traumatic loss of joint function
- Failed osteotomies, hemiarthroplasties and unicondylar implants

The iDuo 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 the above noted conditions.

The iDuo implant is intended for cemented use only.

Identification of the Legally Marketed Device(s) (Predicate Device):	<u>ConforMIS iTotal CR Knee Replacement System</u> Device Class: II Product Code: JWH, OOG Regulation Number: 21 CFR 888.3560 510(k) Number: K131467 and K131019 <u>ConforMIS iUni Unicondylar Knee Replacement System</u> Device Class: II Product Code: HSX, OOG Regulation Number: 21 CFR 888.3520 510(k) Number: K121974 and K111916 <u>ConforMIS iDuo Bicompartmental Knee Repair System</u> Device Class: II Product Code: NPJ, OOG Regulation Number: 21 CFR 888.3560 510(k) Number: K093513
Device Description:	ConforMIS knee replacement systems are patient-specific semi-constrained knee implants which consist of a femoral, tibial, and/or patellar components. The products are intended for treatment of severe pain and/or disability of the knee damaged by osteoarthritis or trauma. 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 femoral components of the devices are manufactured from cobalt chromium molybdenum (CoCrMo) alloy. The tibial component includes a metal tray manufactured from CoCrMo alloy and polyethylene inserts manufactured from UHMWPE or an all polyethylene tibial component. The patellar components are manufactured from UHMWPE.

Substantial Equivalence:	The products subject to this premarket notification are substantially equivalent to the predicate devices. The following testing was performed to establish substantial equivalence: • Sterilization Validation to Sterility Assurance Level (SAL) of $1x10^{-6}$ • Ethylene Oxide (EO) Residual Testing • Product and packaging compatibility with ethylene oxide sterilization

Device Comparison

Attribute	Predicate Devices • iTotal CR Knee Replacement System (K131467 and K131019) • iUni Unicondylar Knee Replacement System (K121974 and K111916) • iDuo Bicompartmental Knee Repair System (K093513)	Modified Device (This submission) • iTotal CR Knee Replacement System • iUni Unicondylar Knee Replacement System • iDuo Bicompartmental Knee Repair System
Materials	• Femoral Implant: CoCrMo • Tibial Implant o All Poly Tibial component - UHMWPE o Metal Backed Tibial Components: o Tibial tray: CoCrMo o Tibial Inserts: UHMWPE • Patellar Component: UHMWPE	• Same
Design & Principle of Operation	• Knee joint semi-constrained cemented prosthesis • Cemented Use Fixed Bearing Design	• Same
Indications for Use	<u>iTotal</u> The iTotal CR Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis. The Indications for Use include: • Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee. • Post traumatic loss of joint function. • Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. • Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants. • Revision procedures provided that	• Same

Attribute	Predicate Devices • iTotal CR Knee Replacement System (K131467 and K131019) • iUni Unicondylar Knee Replacement System (K121974 and K111916) • iDuo Bicompartmental Knee Repair System (K093513)	Modified Device (This submission) • iTotal CR Knee Replacement System • iUni Unicondylar Knee Replacement System • iDuo Bicompartmental Knee Repair System
	anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. This implant is intended for cemented use only. **<u>iUni</u>** 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. **<u>iDuo</u>** The ConforMIS iDuo 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	• Same • Same

Attribute	Predicate Devices • iTotal CR Knee Replacement System (K131467 and K131019) • iUni Unicondylar Knee Replacement System (K121974 and K111916) • iDuo Bicompartmental Knee Repair System (K093513)	Modified Device (This submission) • iTotal CR Knee Replacement System • iUni Unicondylar Knee Replacement System • iDuo Bicompartmental Knee Repair System
	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 : • Painful joint disease due to osteoarthritis • Traumatic arthritis of the knee • Post traumatic loss of joint function • Failed osteotomies, hemiarthroplasties and unicondylar implants The iDuo 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 the above noted conditions. The iDuo implant is intended for cemented use only.	
Patient Matched implants and instruments	• Yes	• Same
Instrumentation	• Patient specific Nylon jigs	• Same
Packaging	Device components are double-pouched using Tyvek®/film pouches which are sealed and labeled	• Same
Sterility Method/ Assurance Level	VHP Gas Plasma with SAL of $1x10^{-6}$	VHP Gas Plasma with SAL of $1x10^{-6}$ and Ethylene oxide with SAL of $1x10^{-6}$
Initial Shelf-Life	6 months	• Same
Labeled Non-	No	• Same

Attribute	Predicate Devices	Modified Device (This submission)
	• iTotal CR Knee Replacement System (K131467 and K131019) • iUni Unicondylar Knee Replacement System (K121974 and K111916) • iDuo Bicompartmental Knee Repair System (K093513)	• iTotal CR Knee Replacement System • iUni Unicondylar Knee Replacement System • iDuo Bicompartmental Knee Repair System
pyrogenic		

Description and Conclusion of Testing	**Nonclinical Testing:** The determination of substantial equivalence for these devices was based on a detailed device description. The following non-clinical laboratory testing was performed demonstrating that the devices are safe and can be considered substantially equivalent to the predicate devices for the intended use: • Sterilization Validation testing to establish a SAL of $1x10^{-6}$ • EO residual testing • Product and packaging compatibility with ethylene oxide sterilization
Safety and Performance	The determination of substantial equivalence for these devices was based on a detailed device description. Non-clinical laboratory testing was performed demonstrating that the devices are safe and can be considered substantially equivalent to the predicate devices for the proposed intended use. Clinical data is not necessary to demonstrate substantial equivalence.
Conclusion	Based on the testing conducted it is concluded that the modified devices are substantially equivalent to the predicate devices and can be sterilized to a SAL of $1x\ 10^{-6}$ using ethylene oxide sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 9, 2014

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

Re: K133256
Trade/Device Name: ConforMIS® iTotal Cruciate Retaining Knee Replacement System (iTotal CR KRS), ConforMIS® iUni Unicondylar Knee Replacement System, ConforMIS® iDuo Bicompartmental Knee Repair System (iDuo KRS)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, HSX, NPJ, OOG
Dated: October 22, 2013
Received: October 23, 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" (21 CFR 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,

Ronald P. Jean -S for

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

Enclosure

iTotal CR Knee Replacement System

510(k) Number (if known): K133256

Device Name: ConforMIS® iTotal Cruciate Retaining Knee Replacement System (iTotal CR KRS)

Indications for Use:

The iTotal® CR Knee Replacement System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis. The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.
- 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___ 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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

iUni Unicondylar Knee Replacement System

510(k) Number (if known): K133256

Device Name: ConforMIS® iUni Unicondylar Knee Replacement 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

iDuo Bicompartmental Knee Replacement System

510(k) Number (if known): K133256

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

Indications for Use:

The ConforMIS iDuo Bicompartmental Knee Repair System is intended for use in patients with severe knee joint pain and disability whose conditions cannot be solely addressed by 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:

- Painful joint disease due to osteoarthritis
- Traumatic arthritis of the knee,
- Post traumatic loss of joint function
- Failed osteotomies, hemiarthroplasties, and unicondylar implants.

The iDuo 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 the above noted conditions.

The iDuo implant 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)

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Casey L. Hanley, Ph.D.

Division of Orthopedic Devices