March 13, 2020

Conformis, Inc.
Nancy Giezen
Manager Regulatory Affairs
600 Technology Park Drive
Billerica, Massachusetts 01821

Re: K193105
Trade/Device Name: iUni Unicondylar Knee Replacement System, iDuo Bicompartmental Knee Repair System, iTotal CR Knee Replacement System, iTotal PS Knee Replacement 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: JWH, OIY, OOG, NPJ, HSX
Dated: January 8, 2020
Received: January 14, 2020

Dear Nancy Giezen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Dr.Ting Song, PhD, RAC
Acting Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)* K193105

Device Name
iUni Unicondylar Knee Replacement System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
iDuo Bicompartmental Knee Repair System

Indications for Use *(Describe)*
The ConforMIS iDuo Bicompartmental Knee Repair System is intended for use in patients with severe knee joint pain and disability whose conditions cannot be solelyaddressed 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 Duo 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*PRAStaff@fda.hhs.gov*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
iTotal Posterior Stabilized (PS) Knee Replacement System

Indications for Use *(Describe)*

The iTotal PS 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, polyarthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity.
- 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
iTotal Cruciate Retaining (CR) Knee Replacement System

Indications for Use *(Describe)*
The iTotal Cruciate Retaining (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 anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

This implant is intended for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510(k) SUMMARY

**Submitter's Name and Address:** Conformis, Inc.
600 Technology Park Drive
Billerica, MA 01821

**Establishment Registration Number(s):** 3009844603 and 3004153240

**Date Summary was Prepared:** November 5, 2019

**Contact Person:** Nancy Giezen
Manager Regulatory Affairs
Telephone: 781-345-9058

**Trade/Device Name(s):**
iUni Unicondylar Knee Replacement System
iDuo Bicompartmental Knee Repair System
iTotal Cruciate Retaining (CR) Knee Replacement System
iTotal Posterior Stabilized (PS) Knee Replacement System

**Common Name:**
Knee Replacement System

**Device Class:**
Class II

**Regulation Numbers:**
888.3560
888.3520

**Classification Names and Product Codes:**
iUni
Prosthesis, knee, femorotibial, nonconstrained, cemented, metal/polymer Knee Arthroplasty Implantation System; OOG, HSX

iDuo
Prosthesis, Knee, Patellofemorotibial, Partial, Semi-Constrained, Cemented, Polymer/Metal/Polymer Knee Arthroplasty Implantation System; NPJ

iTotal CR and PS
Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented,
Polymer/Metal/PolymerKnee Arthroplasty Implantation System; JWH, OIY, OOG

**Legally Marketed Predicate Device**
**(Primary Predicate):**
iTotal Cruciate Retaining (CR) Knee Replacement System (K180906)

**(Ssecondary Predicates):**
iUni Unicondylar Knee Replacement System (K132640, K133256)
iDuo Bicompartmental Knee Replacement System (K093513, K133256)
iTotal Posterior Stabilized (PS) Knee Replacement System (K161668)

**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 ortrauma.

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.

**Indications for Use:**
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 ConforMlS iDuo Bicompartmental Knee Repair System is intended for use in patients with

severe knee joint pain and disability whose conditions cannot be solelyaddressed 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 Duo 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.

iTotal CR
The iTotal Cruciate Retaining (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 anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.
This implant is intended for cemented use only.

iTotal PS
The iTotal PS 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, polyarthritis or osteonecrosis of the knee.
• Post traumatic loss of joint function.
• Moderate varus, valgus or flexion deformity.

• 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.

**Technological Characteristics:**
The subject devices were compared to the predicates and the design features, materials, sizes and methods of sterilization (EO, VHP, steam) are identical. This 510(k) adds the option to sterilize device components using the Steris VHP LTS-V sterilizer.

**Non-Clinical Performance Evaluation:**
The following non-clinical laboratory testing was performed, confirming that the device components are effectively sterilized using Vaporized Hydrogen Peroxide.

• Sterilization Validation testing to establish a SAL of 1x10-6
• VHP residual testing
• Product and packaging compatibility with VHP sterilization

**Conclusion:**
Based on the testing conducted it is concluded that the subject devices are substantially equivalent to the predicate devices and can be sterilized to a SAL of 1x 10-6 ustilizing VHP sterilization.