### 6.0 510(k) SUMMARY

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

**Establishment Registration Number**
3004153240  
3009844603

**Date of Summary**
November 19, 2013

**Contact Person**
Amita S. Shah, Senior Vice President, Regulatory and Quality Affairs

**Telephone Number**
(781) 345-9164

**Fax Number**
(781) 345-0147

**Name of the Device**
ConforMIS iTotal® Cruciate Retaining Knee Replacement System

**Common or Usual Name**
Cruciate Retaining Total Knee Replacement System

**Classification Name**
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

**Regulation Number**
21 CFR 888.3560

**Device Classification**
Product Code:
- JWH – Prosthesis, Knee, Patellofemoral, Semi-Constrained, Cemented, Polymer/Metal/Polymer
- O1Y – Prosthesis, Knee, Patellofemoral, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer +Additive
- OOG – Knee joint patellofemoral 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.
## 510(k) Summary continued

### 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 bicompartamental 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 bicompartamental 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**

### Identification of the Legally Marketed Devices (Predicate Devices)

<table>
<thead>
<tr>
<th>ConforMIS iTotal CR Knee Replacement System (KRS)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Class:</strong></td>
</tr>
<tr>
<td><strong>Product Code:</strong></td>
</tr>
<tr>
<td><strong>Regulation Number:</strong></td>
</tr>
<tr>
<td><strong>510(k) number:</strong></td>
</tr>
<tr>
<td><strong>Device Description</strong></td>
</tr>
<tr>
<td><strong>510(k) Summary</strong></td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td><strong>Substantial</strong></td>
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</tbody>
</table>
| The product subject of this premarket notification is substantially equivalent in design and functionality to the iTotal Cruciate Retaining Knee Replacement System (K131467 cleared July 18, 2013, K131019 cleared May 24, 2013, and K122870 cleared January 14, 2013). The proposed femoral components will be manufactured by an additive manufacturing process using CoCr alloy in a powdered form. The following non-clinical laboratory testing was performed to determine substantial equivalence:
| - Material properties of CoCr implants manufactured by an additive manufacturing process  | - Mechanical properties testing  |
| - Physical properties testing  | - Biocompatibility Testing of implants manufactured by the additive manufacturing process  |
| - Performance testing of femoral implants manufactured through the additive manufacturing process  | - Fatigue testing  |
| - Contact stress/area testing  | All testing has demonstrated the device is substantially equivalent to the predicate devices.  |
510(k) Summary continued:
Device Comparison

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>iTotal CR KRS with femoral component manufactured via an additive manufacturing process (This submission)</th>
<th>Predicate iTotal CR KRS (K131467, K131019 and K122870)</th>
</tr>
</thead>
</table>
| Indication 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 unicompartmental, patellofemoral or bicompartamental 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 unicompartmental implants.  
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. | 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 unicompartmental, patellofemoral or bicompartamental prosthesis. The indications for use include:  
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- 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 unicompartmental, patellofemoral or bi-compartamental implants.  
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. |
| Intended for Cemented Use Only                      | Yes                                                                                                       | Yes                                                                                                       |
| Product Classification                              | 21 CFR 888.3560 (JWH)                                                                                     | 21 CFR 888.3560 (JWH)                                                                                     |
| Design                                              | Knee joint patellofemorotibial semi-constrained cemented prosthesis                                        | Knee joint patellofemorotibial semi-constrained cemented prosthesis                                        |
| Tibial Implant                                      | • Configuration: Metal Backed Tibial Implant  
• Tibial Insert UHMWPE or Vitamin E infused highly cross-linked UHMWPE  
• Single or Dual Inserts  
• Insert sizes: 5-16mm  
• Profile: patient specific | • Configuration: Metal Backed Tibial Implant  
• Tibial Insert UHMWPE or Vitamin E infused highly cross-linked UHMWPE  
• Single or Dual inserts  
• Insert sizes: 5-16mm  
• Profile: patient specific |
<table>
<thead>
<tr>
<th></th>
<th>Femoral Implant</th>
<th>Patella Implant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• CoCr - cast, wrought or additive manufacturing process</td>
<td>• CoCr - cast or wrought material</td>
</tr>
<tr>
<td></td>
<td>• Patient specific</td>
<td>• Patient specific</td>
</tr>
<tr>
<td>Patella Implant</td>
<td>• UHMWPE or</td>
<td>• UHMWPE or</td>
</tr>
<tr>
<td></td>
<td>• Vitamin E infused highly cross-linked UHMWPE</td>
<td>• Vitamin E infused highly cross-linked UHMWPE</td>
</tr>
<tr>
<td>Instrumentation</td>
<td>Patient specific Nylon jigs</td>
<td>Patient specific Nylon jigs</td>
</tr>
<tr>
<td>Principle of Operation</td>
<td>Cemented use</td>
<td>Cemented use</td>
</tr>
<tr>
<td></td>
<td>Fixed Bearing Design</td>
<td>Fixed Bearing Design</td>
</tr>
<tr>
<td>Posterior Cruciate</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ligament (PCL) Sparing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient-Matched</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Packaging</td>
<td>Device components are individually double pouched using Tyvek®/film pouches which are sealed and labeled</td>
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</tr>
<tr>
<td>Sterility Method/</td>
<td>VHP Gas Plasma 1x10^{-6}</td>
<td>VHP Gas Plasma 1x10^{-6}</td>
</tr>
<tr>
<td>Assurance Level</td>
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<td></td>
</tr>
<tr>
<td>Initial Shelf-Life</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Labeled Non-pyrogenic</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Traditional 510(k) – Modified iTotal® CR KRS – Additive manufacturing
510(k) Summary continued

Description and Conclusion of Testing

The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. Testing on the femoral components manufactured from an additive manufacturing process is outlined below:

- Material properties tests
- Mechanical properties testing
- Biocompatibility tests
- Contact area/contact stress testing
- Fatigue testing of femoral implant

Test results demonstrated that the device is safe and can be considered substantially equivalent to the predicate device for the intended use.

Safety and Performance

The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. The testing demonstrated that the device is safe for its intended use and can be considered substantially equivalent to the predicate devices. Clinical data is not necessary to demonstrate substantial equivalence.

Conclusion

Based on the testing conducted, it is concluded that the iTotal Cruciate Retaining Knee Replacement System with femoral components made from an additive manufacturing process is substantially equivalent to the iTotal Cruciate Retaining Knee Replacement System (K131467, K131019 and K122870)
March 28, 2014

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

Re: K133560
   Trade/Device Name: iTotal CR 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, O1Y, OOG
   Dated: March 3, 2014
   Received: March 4, 2014

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,

Lori A. Wiggins

for
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): K133560

Device Name: iTotal CR Knee Replacement System

Indications for Use:

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 unicompartmental, patellofemoral or bicondylar 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.
- Sufficient varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthroplasties, and unicompartmental, patellofemoral or bicondylar 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

Traditional 510(k) – Modified iTotal® CR KRS – Additive manufacturing