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U.S. FOOD & DRUG ADMINISTRATION

April 19, 2021

Conformis Inc.
Mary Kruitwagen
Sr. Regulatory Affairs Specialist
600 Technology Park Drive, 4th Floor
Billerica, Massachusetts 01821

Re: K203421
Trade/Device Name: Triathlon AS-1
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Codes: OOG, JWH
Dated: March 30, 2021
Received: April 1, 2021

Dear Mary Kruitwagen:

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2021.04.19 13:33:19 -04'00'

For: Ting Song, Ph.D., R.A.C.
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)*
K203421

Device Name
Triathlon AS-1

Indications for Use *(Describe)*

The Triathlon AS-1 patient specific cutting guides are disposable, single-use surgical instruments intended to assist orthopedic surgeons in the positioning of femoral and tibial total knee arthroplasty components intraoperatively, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. They are intended for use with the Cruciate Retaining (CR), Condylar Stabilizing (CS), Posterior Stabilized (PS) and Tritanium® components of the Triathlon® Total Knee System and the Total Stabilizer (TS) and Posterior Stabilized Rotation (PSR) Triathlon® tibial inserts.

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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CONFORMIS

# 510(k) Summary for Triathlon AS-1

K203421

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| 510(k) Number: | |
| Submitter's Name and Address: | Conformis, Inc.<br>600 Technology Park Drive, Fourth Floor<br>Billerica, Massachusetts 01821<br>USA<br><br>Main Telephone number: 781-345-9164<br>Main Fax Number: 781-345-0147 |
| Establishment Registration Numbers(s): | 3009844603 and 3004153240 |
| Date Summary Prepared: | November 16, 2020 |
| Contact Person: | Mary Kruitwagen<br>Title: Senior Regulatory Affairs Specialist<br>Telephone: 781-345-9038<br>Fax: 781-345-0147<br>Email: Mary.Kruitwagen@conformis.com |
| Secondary Contact: | Kara Johnson<br>Title: Director Regulatory Affairs<br>Telephone: 781-832-5402<br>Fax: 781-345-0147<br>Email: Kara.Johnson@conformis.com |
| Trade Name/Device Name: | Triathlon AS-1 |
| Common/ Usual Name: | Knee Arthroplasty Implantation System |
| Device Class: | II |
| Regulation Number: | 21 CFR 888.3560 |
| Regulation Description: | Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. |
| Product Code: | OOG, JWH |
| Product Code Regulation : | 21 CFR 888.3560 |
| Product Code Device Name: | Knee Arthroplasty Implantation System |
| Legally Marketed Predicate Device:<br>Primary Predicate: | 510(k): K180906<br>Device: iTotal® Cruciate Retaining (CR) Knee Replacement System<br>SE Date: May 16, 2018<br>Product codes: JWH, OIY, OOG<br>Class: II |

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| Legally Marketed Predicate Device: | 510(k): | K201023 |
| Secondary Predicate: | Device: | iTotal® Identity Posterior Stabilized Knee Replacement System |
| | SE Date: | June 16, 2020 |
| | Product codes: | JWH, OIY, OOG |
| | Class: | II |

Device Description:

The subject device, Triathlon AS-1, is a new Conformis Inc. device offering. The Triathlon AS-1 is comprised of patient matched single-use disposable cutting guides (also referred to as instruments or jigs) with corresponding surgical documentation which includes the Instructions for Use, Surgical Protocol and Surgical Plan. The single-use patient-matched instruments (including documentation) are similar to those of the legally marketed predicate device Knee Replacement Systems by Conformis Inc. (predicate devices K180906, K201023).

The subject device, Triathlon AS-1, does not include an implant or reusable instrumentation associated with knee replacement systems. The subject device, however, is designed to be compatible with selected legally marketed Triathlon Total Knee implants and reusable instrumentation from Stryker Orthopaedics. While no implant is part of this subject device, the subject device utilizes software to determine the size and position of the compatible implant for an individual patient and then design the subject device around the patient's anatomy to prepare for the identified implant.

For the subject device, the predicate Conformis design software, surgical plan, and single-use cutting guides (instrumentation) are being modified to accurately size, position, and prepare the bone for off-the-shelf Triathlon femoral and tibial implants. Using patient imaging (CT scans), a Triathlon Total Knee implant set is sized and positioned to best meet the unique anatomic requirements of the specific patient. The Triathlon AS-1 planning process allows for efficient 3D planning, providing optimized fit of an off-the-shelf Triathlon implant and providing the design of the patient-matched, single-use guides to prepare for the planned implant in the planned position.

Jigs are designed to fit the contours of the patient's femoral and tibial anatomies and to facilitate a simpler surgical technique. The design of the instrumentation will be modified as needed to be compatible with the Stryker Orthopaedics Triathlon manual surgical instrumentation.

Each set of instruments is designed for single use, specifically for one patient. The disposable single-use instrument set is manufactured from biocompatible nylon material and supplied sterile.

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| Indications For Use: | The Triathlon AS-1 patient-specific cutting guides are disposable, single-use surgical instruments intended to assist orthopedic surgeons in the positioning of femoral and tibial total knee arthroplasty components intraoperatively, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. They are intended for use with the Cruciate Retaining (CR), Condylar Stabilizing (CS), Posterior Stabilized (PS) and Tritanium® components of the Triathlon® Total Knee System and the Total Stabilizer (TS) and Posterior Stabilized Rotation (PSR) Triathlon® tibial inserts. |
| Summary of Intended Use/Indications for Use Differences | The subject device, single-use patient-matched instruments and the corresponding surgical documentation, is similar to the predicate iJigs provided with the Conformis Total Knee Replacement Systems. The predicate devices describe these similar instruments (iJigs) in their premarket submissions. The subject device performs the same function and has the same intended use as the iJigs in the predicate devices.<br><br>The modifications to the single-use patient matched instruments do not raise any new issues with the safety or effectiveness as compared to the predicate single-use patient matched instruments. The cemented or uncemented implant fixation method has no bearing on the subject device.<br><br>The differences in the wording of the subject device's Intended Use/Indications For Use statements do not represent a change from the Indications For Use or Intended Use of the predicate devices for the equivalent single-use patient matched instruments. |
| Summary of Technological Characteristics | There is no new technology employed as part of this subject device.<br><br>The CAD design processes for the subject device are the similar to those employed for the predicate devices. The instrumentation has the same function and technological characteristics as those of the predicate devices. The subject device is composed of the same material that uses the same selective laser sintering manufacturing process as the predicate devices. The subject device uses the same packaging materials and sterilization methods as those of the predicate devices. |
| Substantial Equivalence: | The subject device is substantially equivalent to the predicate devices Conformis Total Knee Replacement System as described in their premarket submissions (K180906 and 201023). The following testing was conducted and used to establish substantial equivalence:<br>• Cadaver testing (surgeon evaluation and usability)<br>• Implant sizing and positioning testing<br>• Software verification and validation |
| Safety and Effectiveness Data | The assessment of the non-clinical data provided in this submission supports that the subject device is safe, effective and performs as well |

as the predicate device. No new issues of safety or effectiveness were raised.

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| Conclusion: | In conclusion, the information contained within this submission supports safety, effectiveness of this device and that it performs as well as the predicate device. |