DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 3, 2016

CORIN USA
Kathy Trier, Ph.D.
Global VP Regulatory and Clinical Affairs
5670 West Cypress Street, Suite C
Tampa, Florida 33607

Re: K152893
Trade/Device Name: Corin Optimized Positioning System (OPS)
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH, LWJ
Dated: April 26, 2016
Received: April 27, 2016

Dear Dr. Trier:

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 Parts 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 Industry and Consumer Education 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 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 Industry and Consumer Education 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

2. INDICATIONS FOR USE

510(k) Number (if known): K152893

Device Name: Corin Optimized Positioning System (OPS)

Indications for Use:

The Corin Optimized Positioning System (OPS) is intended to be used as patient-specific surgical instrument to assist in the alignment of components during total hip arthroplasty. The Corin OPS is intended to assist in the orientation of the acetabular cup intra-operatively using anatomical landmarks of the pelvis that are clearly identifiable on preoperative X- rays and CT imaging scans.

The Optimized Positioning System including the Patient Specific Guides is intended for use with the Corin Trinity Acetabular System (K093472, K110087, K111481, K122305, K123705, K130128, K130343 and K131647) for total hip arthroplasty.

The Corin Optimized Positioning System is intended for use with the Direct Anterior or Posterolateral surgical approaches.

The Patient Specific Guides are intended for single 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2. 510(K) SUMMARY

1. **Applicant/Sponsor:** Corin USA
   Distributor 5670 W. Cypress
   Street Suite C
   Tampa, Florida 33607
   Establishment Registration No.: 1056629

2. **Manufacturer:** Optimized Ortho Pty Ltd
   17 Bridge Street
   Pymble NSW 2073
   Australia
   Establishment Registration No: None

3. **Contact Person:**

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4. **Date:** April 21st 2016

5. **Proprietary Name:** Corin Optimized Positioning System (OPS)

6. **Common Name:** Hip Prosthesis

7. **Product Code(s):** LZO, MEH, LWJ

8. **Classification Name:**

   888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

9. Legally Marketed Devices to which Substantial Equivalence is claimed:

- Materialise N.V. - Signature™ Personalized Patient Care System (K111863)
- Corin - Trinity Acetabular System (K093472, K110087, K111481, K122305, K123705, K130128, K130343, K131647)
- Corin Instrument 510(k) Exempt (Product Code - KIL)
- Reference Predicate Device - Medacta Pedicle Screw Placement Guides (K132788)

10. Device Description:

The Corin Optimized Positioning System (OPS) consists of software and hardware components to assist the surgeon in the alignment of components during Total Hip Arthroplasty.

The software component assists the surgeon in determining a patient specific target orientation for the acetabular cup through a pre-operative patient specific analysis and two patient specific reports: Functional Hip Analysis (FHA) report and Patient Specific Visualisation (PSV) report.

The hardware components assist the surgeon in delivering the target orientation through the use of a Patient Specific Guide and bone model (replica of the patient's acetabulum, into which the guide fits), and associated reusable instrumentation.

The Corin OPS can be used with the Trinity Acetabular System and the respective compatible components.

11. Intended Use / Indications:

The Corin Optimized Positioning System (OPS) is intended to be used as patient-specific surgical instrument to assist in the alignment of components during total hip arthroplasty. The Corin OPS is intended to assist in the orientation of the acetabular cup intra-operatively using anatomical landmarks of the pelvis that are clearly identifiable on preoperative X- rays and CT imaging scans.

The Optimized Positioning System including the Patient Specific Guides is intended for use with the Corin Trinity Acetabular System (K093472, K110087, K111481, K122305, K123705, K130128, K130343 and K131647) for total hip arthroplasty.
The Corin Optimized Positioning System is intended for use with the Direct Anterior or Posterolateral surgical approaches.

The Patient Specific Guides are intended for single use only.

12. Non-Clinical Testing:

Non-clinical testing was performed to assess the safety and effectiveness of the device. Testing included biocompatibility testing of the raw material performed by the raw material supplier according to ISO 10993. Mechanical and performance testing was also performed on the Patient Specific Guides to ensure that the devices are able to withstand the conditions that may be encountered during storage, shipping, distribution and normal use including drop testing for damage or fracture, flexural creep, cleaning and sterilization, packaging and shelf life validation. A cadaver study was performed to measure the repeatability (intra-observer variability) and reproducibility (inter-observer variability) of the system to verify the performance of the system was adequate to perform as intended and to assure the system accuracy of implanted cup orientation relative to the pre-operative plan. Software verification and validation was completed in accordance with FDA guidance including *General Principles of Software Validation; Final Guidance for Industry and FDA Staff and Guidance for Industry, FDA Reviewers* and *Compliance on Off-The-Shelf Software Use in Medical Devices*. Testing was also performed to verify that the FHA software module and acetabular guide design is reproducible and repeatable when processed by multiple operators. Cleaning and sterilization validation of the re-usable instruments was completed. Testing verified that the accuracy and performance of the device is adequate to perform as intended.

13. Clinical Testing:

Clinical testing was not necessary for this Traditional 510(k).

14. Summary of Technologies/Substantial Equivalence:

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.