Corin USA Limited
Rachel King
Regulatory Affairs Associate
12750 Citrus Park Lane
Tampa, Florida 33625

June 15, 2018

Re: K172551
Trade/Device Name: Corin Trinity™ PLUS Acetabular Shell
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, OQG, OQI, MBL
Dated: May 16, 2018
Received: May 17, 2018

Dear Ms. King:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K172551

Device Name
Corin Trinity™ PLUS Acetabular Shell

Indications for Use *(Describe)*
The indications for the Corin Trinity™ PLUS Acetabular Shell as a total hip arthroplasty include:
o Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
o Rheumatoid arthritis,
o Correction of functional deformity,
o Revision of previously failed total hip arthroplasty
o Developmental dysplasia of the hip (DDH),

The Trinity™ PLUS Acetabular Shell is indicated for cementless 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

3. 510(K) SUMMARY

1. Applicant/Sponsor:

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Registration No.: 1056629

2. Contact Person:

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3. Date: June 13, 2018

4. Proprietary Name: Corin Trinity™ PLUS Acetabular Shell

5. Common Name: Hip Prosthesis

6. Product Codes: LPH, LZO, OQG, OQI, MBL

7. Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21CFR 888.3358)

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

- Corin Trinity™ Acetabular System (K093472, K110087, K122305 and K130128) (Primary predicate)
- Biomet G7 OsseoTi (K140669)

9. Device Description:

The Trinity™ PLUS Acetabular Shell is a component of a modular acetabular cup system consisting of a hemispherical press fit, titanium alloy shell for use with cobalt chrome alloy (Dual Mobility articulations only) or polyethylene liners and a dedicated range of ceramic and cobalt chrome alloy modular 12/14 taper femoral heads providing ceramic on polyethylene and metal on polyethylene articulations for use in total hip replacement procedures using any Corin femoral stem with a 12/14 taper connection. The acetabular shell has an outer porous structure produced by additive manufacturing using titanium alloy powder (ASTM F3001). The shell is available with or without a layer of electrochemically deposited biomimetic calcium phosphate coating. The Trinity™ PLUS acetabular shell is available with or without screw holes which permit the use of dedicated titanium screws to provide additional fixation if required.

The Trinity™ PLUS Acetabular shell is intended for use in primary and revision total hip arthroplasty to provide increased stability and reduce pain by replacing the hip joint articulation where there is evidence of sufficient bone to seat and support the components.

10. Intended Use / Indications:

The indications for the Corin Trinity™ PLUS Acetabular Shell as a total hip arthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision of previously failed total hip arthroplasty
- Developmental dysplasia of the hip (DDH),

The Trinity™ PLUS Acetabular Shell is indicated for cementless use only.

11. Summary of Technologies/Substantial Equivalence:

The Corin Trinity™ PLUS Acetabular Shell is similar in terms of intended use, indications and materials as the predicates (K093472, K110087, K122305, K130128 and K140669). The range of sizes available for the Corin Trinity™ PLUS Acetabular Shell is similar to the range cleared for the Corin Trinity™ Acetabular System predicate devices.

The outer porous structure, produced by an additive layer manufacture technique, of the Corin Trinity™ PLUS Acetabular Shell is similar to the predicate Biomet G7 OsseoTi (K140669).

The inner shell incorporates the Corin Trinity™ Acetabular Shell design, dimensions, and locking mechanisms. The electrochemically deposited calcium phosphate coating on the Corin Trinity™ PLUS Acetabular Shell is identical to that on the Corin Trinity™ Acetabular System (K093472, K110087, K122305 and K130128). Based on these similarities, Corin believes that the Trinity™ PLUS Acetabular Shell is substantially equivalent to the predicate devices.

12. Non-Clinical Testing:

Previous testing was completed on the Trinity™ Acetabular System (K093472, K110087, K122305 and K130128), to support substantial equivalence. This testing is applicable to the Trinity™ PLUS Acetabular Shells as the sizing is similar and the liner mating features are identical.

Non-clinical testing conducted to demonstrate substantial equivalence includes static tests (Shear, Tensile, compression), Dynamic Tests (Deformation, Taper Abrasion, Bending Fatigue, Shear Fatigue, Range of Motion, Impingement, Shell Fatigue), Porous Structure Characterization and Animal Data.

Bacterial Endotoxin Testing (BET) has been conducted on finished, sterilised product, using Limulus Amebocyte Lystate (LAL) kinetic chromogenic methodology.

13. Clinical Testing

Clinical testing was not necessary to determine substantial equivalence between the Trinity™ PLUS Acetabular Shell and the predicate devices.

The culmination of the results of the mechanical testing, characterization and animal data indicate that the devices perform within their intended use and are substantially equivalent to the predicate devices.