



June 5, 2025

Corin USA Limited
Aaron Brunt
Regulatory Affairs Manager
12750 Citrus Park Lane
Tampa, Florida 33625

Re: K242744

Trade/Device Name: Trinity EVO 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: September 11, 2024

Received: May 1, 2025

Dear Aaron Brunt:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
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

Indications for Use

Submission Number (if known)

K242744

Device Name

Trinity EVO Acetabular Shell

Indications for Use (Describe)

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

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis.
- Correction of functional deformity.
- Developmental dysplasia of the hip (DDH)/Congenital dislocation of the hip (CDH)

The Trinity™ EVO acetabular shell is also indicated for use in revisions of a previously failed total hip arthroplasty.

The Trinity™ EVO 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.

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Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Corin USA Limited
Applicant Address	12750 Citrus Park Lane Tampa FL 33625 United States
Applicant Contact Telephone	+4407970237346
Applicant Contact	Mr. Aaron Brunt
Applicant Contact Email	aaron.brunt@coringroup.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Trinity EVO Acetabular Shell
Common Name	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented
Classification Name	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulation Number	888.3358
Product Code(s)	LPH, LZO, OQG, OQI, MBL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172551	Trinity PLUS Acetabular Shell	LPH
K181366	REDAPT Porous Acetabular Shell	LPH

Device Description Summary

21 CFR 807.92(a)(4)

The Trinity™ EVO acetabular shell forms part of a modular acetabular system. The Trinity™ EVO acetabular shell is a hemispherical press fit titanium alloy shell for use with cobalt chrome alloy (Trinity™ Dual Mobility 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 arthroplasty (THA) procedures using compatible Corin femoral stems with a 12/14 taper connection.

The Trinity™ EVO acetabular shell has a porous structure manufactured from titanium alloy powder, produced via additive manufacturing using Laser Powder Bed Fusion (LPBF), and is available with or without an additional layer of electrochemically deposited calcium phosphate. The Trinity™ EVO acetabular shell is provided with screw holes permitting the use of dedicated titanium bone screws to provide additional fixation, if required. The Trinity™ EVO acetabular shell is also available without screw holes. A titanium occluder is provided to occlude the apical introducer hole.

The Trinity™ EVO acetabular shell is intended for use in primary and revision THA in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged hip joint articulation when there is evidence of sufficient sound bone to seat and support the components.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis.
- Correction of functional deformity.
- Developmental dysplasia of the hip (DDH)/Congenital dislocation of the hip (CDH)

The Trinity™ EVO acetabular shell is also indicated for use in revisions of a previously failed total hip arthroplasty.

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Trinity™ EVO Acetabular Shell, subject of this submission, has the same indications for use as those used in the primary predicate device (KI 72551). Trinity™ EVO Acetabular Shell also has similar indications for use as those referenced in REDAPT Porous Acetabular Shell (KI 81366).

Technological Comparison

21 CFR 807.92(a)(6)

The Trinity™ EVO Acetabular Shell uses similar materials to the predicate Trinity™ PLUS Acetabular Shell (KI 72551). The range of sizes available for the Trinity™ EVO Acetabular Shell is identical to the range cleared for the predicate device.

The outer porous structure, produced by an additive manufacture technique, of the Trinity™ EVO Acetabular Shell is similar to the predicate.

The inner shell incorporates the Corin Trinity™ Acetabular Shell design, dimensions, and locking mechanisms. The electrochemically deposited calcium phosphate coating on the Corin Trinity™ EVO Acetabular Shell is similar to that on the predicate.

The Trinity™ EVO Acetabular Shell also has similar sizes and dimensions, and is manufactured from similar material (Ti6Al4V) to those used in the secondary predicate, REDAPT Porous Acetabular Shell (KI 81366). The REDAPT Porous Acetabular Shell predicate is primarily for residual powder comparison.

Based on these similarities, Corin believes that the Trinity™ PLUS Acetabular Shell is substantially equivalent to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Previous testing was completed on the Trinity™ PLUS Acetabular Shell {K172551} to support substantial equivalence. This testing is applicable to the Trinity™ EVO Acetabular Shells as the sizing and the liner mating features are identical.

Non-clinical testing conducted to demonstrate substantial equivalence includes:

• Static Tests

- Static Shear as per ASTM F1044-05(2017)
- Compression as per ISO 13314:2011
- Deformation testing as per ISO 7206-12:2016
- Deformation testing with bone foam as per internal protocol
- Liner Disassembly as per ASTM F1820-22
- Roughness testing as per DIN EN ISO 4287:1998+A1:2009

• Dynamic Tests

- Taber Abrasion as per ASTM F1978-22
- Shell Fatigue per ASTM F3090-20
- Cadaveric Testing as per internal protocol
- Porous Structure Characterization as per ASTM F1854-15
- Residual Powder Gravimetric Testing as per ASTM F2459-18
- MicroCT Porous Structure Characterization as per internal protocol
- Screw Pull Through Testing as per internal protocols
- Bacterial Endotoxin Testing (BED conducted on finished, sterilized product, using Limulus Amoebocyte Lysate (LAL) kinetic chromogenic methodology

Not applicable

Specific mechanical and characterization testing was performed by Corin on the Trinity™ EVO Acetabular Shell. The results of this testing show that the Trinity™ EVO Acetabular Shell is substantially equivalent to the predicate devices. A comparison of indications for use and contraindications also demonstrated substantial equivalence.