October 3, 2024

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

Re: K241472
Trade/Device Name: Icona Hip Stem
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: MEH, KWL, KWY, LZO
Dated: May 24, 2024
Received: September 6, 2024

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,

Limin Sun -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241472

Device Name
Icona Hip Stem

Indications for Use *(Describe)*
The indications for the Corin Icona Hip Stem as a total hip arthroplasty, and when used in combination with a Corin hemiarthroplasty head, as a hip hemiarthroplasty, include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union and femoral neck fractures
- Developmental dysplasia of the hip (DDH) / congenital dysplasia of the hip (CDH)

The Corin Icona Hip Stem 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.

510(k) #: K241472

510(k) Summary

Prepared on: 2024-10-03

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	Icona Hip Stem
Common Name	Femoral Stem
Classification Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulation Number	888.3353
Product Code(s)	MEH, KWL, KWY, LZO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K150862	Actis DuoFix Hip Prosthesis	MEH
K173880	TriFit CF Hip Stem	MEH
K201657	OMNI MOD Hip System	LZO
K212069	Metafix Hip Stem	LZO

Device Description Summary

21 CFR 807.92(a)(4)

The Corin Icona Hip Stem is a tapered stem design manufactured from Titanium alloy (Ti6Al4V) (ASTM F136) with a layer of commercially pure titanium (ISO 5832-2, ASTM F1580) and an additional layer of electrochemically deposited calcium phosphate (ASTM F1609) applied.

The Icona Hip Stem is intended for use in hemiarthroplasty and total hip arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged hip joint articulation where there is evidence of sufficient sound bone to seat and support the components.

The design is a fully-coated titanium femoral hip stem featuring a polished neck with 12/14 tapered male trunnion for assembly with Corin modular femoral head components. Additionally, the Icona stem features a trapezoidal, tripled tapered body, providing for rotational and axial stability.

The Icona Hip Stem is a collared stem available in two different offsets (Standard and Lateralised) and twelve (12) different sizes, totaling 24 options.

The Icona Hip Stem is compatible with the following acetabular systems:
• Traditional – Trinity (K093472, K103120, K110087, K111481, K122305, K123705, K130128, K130343, K131647) and Trinity PLUS (K172551)
• Dual mobility – Trinity Dual Mobility (K170359) and MobiliT (K191831)
• Bipolar – Bipolar-i (K183114)

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The indications for the Icona Hip Stem as a total hip arthroplasty, and when used in combination with a Corin hemiarthroplasty head, as a hip hemiarthroplasty, include:
• Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
• Rheumatoid arthritis
• Correction of functional deformity
• Treatment of non-union and femoral neck fractures
• Developmental dysplasia of the hip (DDH) / congenital dysplasia of the hip (CDH)

The Corin Icona Hip Stem is indicated for cementless use only.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Icona Hip Stem is substantially equivalent to Actis DuoFix Hip Prosthesis (K150862), TriFit CF Hip Stem (K173880), Metafix Hip Stem (K082525, K121439, K153381, K212069), OMNI MOD Hip Stem (K000788, K201657) in terms of intended use and indications, with the exception of OMNI MOD Hip Stem which is also indicated for revision.

Technological Comparison 21 CFR 807.92(a)(6)

The Icona Hip Stem is substantially equivalent to previously cleared predicate device Actis DuoFix Hip Prosthesis (K150862) in terms of material (titanium alloy – Ti6Al4V), triple-taper geometry, neck geometry, collar design and stem sizes.

The Icona Hip Stem is substantially equivalent to previously cleared predicate device TriFit CF (K173880) in terms of material (titanium alloy – Ti6Al4V), coating, taper design and neck geometry.

The Icona Hip Stem is substantially equivalent to previously cleared predicate device OMNI MOD Hip System (K000788, K201657) in terms of material (titanium alloy – Ti6Al4V), neck geometry and finish.

The Icona Hip Stem is substantially equivalent to previously cleared predicate device MetaFix Hip Stem (K082525, K121439, K153381, K212069) in terms of intended use, indications, material (titanium alloy – Ti6Al4V), neck geometry, taper design and packaging.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing and rationales provided to support substantial equivalence include:
- Distal stem fatigue testing (ISO 7206-4)
- Neck fatigue testing (ISO 7206-6)
- Cadaveric evaluation
- Range of motion (ROM) (ISO 21535)
- Impingement performance engineering rationale
- Femoral head disassembly and corrosion performance engineering rationale

No clinical tests were performed to support the safety and effectiveness of the subject device

The results of the specific mechanical testing performed on the Icona Hip Stem show that the device is substantially equivalent to the predicate devices. A comparison of intended use and indications for use also demonstrated substantial equivalence.