July 28, 2021

Corin Ltd.
% Robert Poggie
President
BioVera Inc.
65 Promenade Saint Louis
Notre Dame de LIle Perrot, Quebec J7V 7P2
Canada

Re: K201657
Trade/Device Name: Corin Ltd. Hip Products: Trinity™ Acetabular System, Trinity™ PLUS Acetabular Shell, MetaFix™ Hip System, TriFit™ CF and TS Hip Systems, TaperFit™ Hip System, Revival™ Modular Hip System, MiniHip™, Trinity™ Dual Mobility, MobiliT, BiPolar-i, OMNI MOD™ Hip System, OMNI K1 and K2 Hip Systems, OMNI Bipolar Heads, Corin Biolox Delta Ceramic Heads, OMNI Delta Ceramic Heads
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, LPH, OQI, MEH, KWL, KWY, JDI, OQG, MBL
Dated: June 23, 2021
Received: June 24, 2021

Dear Robert Poggie:

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,

Limin Sun, Ph.D.
Acting 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)*
K201657

Device Name
Corin BiPolar-i

Indications for Use *(Describe)*

The BiPolar-i is intended for use in the following indications: Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis in which the acetabulum does not require replacement, Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur, Revision of failed partial hip replacements in which the acetabulum does not require replacement. The BiPolar-i 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)

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510(k) Number *(if known)*

K201657

Device Name

Corin BIOLOX™ delta

Indications for Use *(Describe)*

The Trinity Acetabular System is indicated for use in non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, correction of functional deformity, developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH). The Trinity Acetabular System is intended for cementless, single 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)

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510(k) Number *(if known)*
K201657

Device Name

Corin MetaFix™ Hip

Indications for Use *(Describe)*

The indications for the Corin MetaFix™ Hip Stem as a total hip arthroplasty, and when used in combination with a Corin hemi arthroplasty head, as a hip hemi-arthroplasty, 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) and congenital dysplasia of the hip (CDH)

The Corin MetaFix™ 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)

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510(k) Number *(if known)*
K201657

Device Name

Corin MiniHip™ Stem

Indications for Use *(Describe)*

The indications for the MiniHip Stem 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) and congenital dysplasia of the hip (CDH)The MiniHip 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)

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510(k) Number *(if known)*
K201657

Device Name

Corin Trinity™ Acetabular System

Indications for Use *(Describe)*

The indications for the Trinity™ Acetabular System 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), and congenital dysplasia of the hip (CDH). The Trinity Acetabular System is intended for cementless, single 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)

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510(k) Number *(if known)*

K201657

Device Name

Corin Trinity™ Dual Mobility

Indications for Use *(Describe)*

The Trinity™ Dual Mobility System is intended for use in the following indications: 1. Non-inflammatory degenerative joint disease, including osteoarthritis & avascular necrosis 2. Rheumatoid Arthritis 3. Correction of functional deformity 4. Revision of previously failed total hip arthroplasty 5. Patients at increased risk of dislocation 6. Developmental dysplasia of the hip (DDH). The TrinityTM Dual Mobility System 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)

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510(k) Number *(if known)*
K201657

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: 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 cement less 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)

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510(k) Number *(if known)*
K201657

Device Name

MobiliT™ Cup and Dual Mobility acetabular cups

Indications for Use *(Describe)*

The MobiliT Cup, for cemented and cementless use, are indicated for primary replacement of the hip joint:
- In degenerative pathologies: primary, secondary or post-traumatic osteoarthritis, rheumatoid arthritis
- For patients who have a high risk of dislocation
- In cases of necrosis of the femoral head
- In cases of fracture of the neck of the femur
- In cases of congenital luxation

The MobiliT Cup, for cemented and cementless use, are indicated for revision when the bone tissue remains sufficient after the removal of the previous acetabular cup.

The cementless MobiliT standard Cup, with flanges or with flanges and hook are indicated for cementless use only.

The cemented MobiliT Cup is indicated for cemented 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)

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# Indications for Use

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*See PRA Statement below.*

510(k) Number *(if known)*
K201657

Device Name

OMNI Bipolar Head

Indications for Use *(Describe)*

The Apex Hip System Bipolar Head is intended for use in combination with an Apex Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate: Femoral neck and trochanteric fractures of the proximal femur, Osteonecrosis of the femoral head, Revision procedures where other devices or treatments for these indications have failed.

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)

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510(k) Number *(if known)*
K201657

Device Name

OMNI Delta Ceramic Femoral Head
The OMNI Hip system Ceramic Femoral Heads

Indications for Use *(Describe)*

The OMNI Hip system Ceramic Femoral Heads are intended for use in combination with the OMNI Hip System Stems as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with the OMNI Interface Acetabular System or bipolar component. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*
*K201657*

Device Name

OMNI MOD and OMNI Modular Hip: OMNI K2 Stem

Indications for Use *(Describe)*

The indications for use of the OMNI Modular Hip Stems in hip arthroplasty include the following conditions, as appropriate:
- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

The OMNI Modular Hip stems are indicated for cementless use only and single use implantation.

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)

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510(k) Number *(if known)*
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Device Name

OMNI MOD™ Hip

Indications for Use *(Describe)*

The indications for use of the OMNI Modular Hip Stems in hip arthroplasty include the following conditions, as appropriate:
- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

The OMNI Modular Hip stems are indicated for cementless use only and single use implantation.

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*

K201657

Device Name

Corin Revival™ Hip

Indications for Use *(Describe)*

The Revival™ Modular Revision Hip Stem is indicated in revision surgery of femoral components, following failure of primary cemented or un-cemented prosthesis. The **REVIVAL™** Modular Hip Stem 100mm distal component is also indicated in primary total hip arthroplasty. The indications for the Revival ™ Modular Revision Hip Stem include: Non-inflammatory degenerative joint disease including primary and secondary osteoarthritis. Rheumatoid arthritis. Correction of functional deformity. Treatment of non-union and femoral neck fractures. Treatment of traumatic dislocations of the hip, Failures of osteotomy, Treatment of arthrodesis. The Revival ™ Modular Revision Hip Stem is indicated for cementless, single 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)

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510(k) Number *(if known)*
K201657

Device Name

Corin TaperFit™

Indications for Use *(Describe)*

TaperFit™ Hip Stem is indicated for the relief of pain and restoration of hip function following the effects of femoral neck fracture, osteo, rheumatoid and inflammatory arthritis, post- traumatic disease effects, avascular necrosis and total hip revision. The TaperFit Hip Stem is indicated for hemi-arthroplasty when used in combination with Corin hemi-arthroplasty femoral heads.

The TaperFit™ Hip Stem is indicated for cemented, single use only.

Type of Use *(Select one or both, as applicable)*

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*See PRA Statement below.*

510(k) Number *(if known)*
K201657

Device Name

OMNI K1 Hip System

Indications for Use *(Describe)*

The indications for use of the K1 Hip Stem in hip arthroplasty include the following conditions, as appropriate: Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis; Rheumatoid arthritis; Correction of functional deformity; Congenital dislocation; Revision procedures where other treatments or devices have failed; Femoral neck and trochanteric fractures of the proximal femur.
The K1 Hip Stem is indicated for cementless use only and single use implantation.

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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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)*
K201657

Device Name

Corin TriFit CF Hip

Indications for Use *(Describe)*

The indications for the TriFit CF Hip Stem as a total hip arthroplasty and 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), Previously failed hip surgery. The TriFit CF 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)

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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)*
K 2016 57

Device Name

Corin TriFit TS™ Hip

Indications for Use *(Describe)*

The indications for the Corin TriFit TS™ Hip as a total hip arthroplasty, and when used in combination with a Corin hemi arthroplasty head, as a hip hemi-arthroplasty, include: Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, Rheumatoid arthritis, Correction of functional deformity, Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur, Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH). The TriFit TS Hip is intended 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)

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# 510(k) SUMMARY

## *Cross Compatibility of Corin Ltd. and OMNIlife Sciences Hip Products*

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness of the subject Corin hip devices.

### A. SUBMISSION CORRESPONDENCE

| | |
|---|---|
| **Prepared By:** | BioVera, Inc. |
| **Submitter Address:** | 65 Promenade Saint-Louis, Notre-Dame-De-L'Ile-Perrot, Quebec, J7V 7P2, CANADA |
| **Contact Person:** | Robert A Poggie, PhD |
| **Phone & Fax Number:** | (514) 901-0796 |
| **Date of Submission:** | June 23, 2021 |

### B. DEVICE IDENTIFICATION & MANUFACTURER (Submission Sponsor)

| | |
|---|---|
| **Manufacturer Name:** | Corin Ltd. |
| **Manufacturer Address:** | 480 Paramount Drive, Raynham, MA, 02767, USA |
| **Registration Number:** | 1226188 |
| **Contact Name:** | Christina Rovaldi |
| **Title:** | Regulatory Affairs Specialist |
| **Device Trade Names:** | Corin Ltd. Hip Products: Trinity™ Acetabular System, Trinity™ PLUS Acetabular Shell, MetaFix™ Hip System, TriFit™ CF and TS Hip Systems, TaperFit™ Hip System, Revival™ Modular Hip System, MiniHip™, Trinity™ Dual Mobility, MobiliT, BiPolar-i, OMNI MOD™ Hip System, OMNI K1 and K2 Hip Systems, OMNI Bipolar Heads, Corin Biolox Delta Ceramic Heads, OMNI Delta Ceramic Heads. |
| **Device Common Names:** | Hip prosthesis, femoral hip stem, acetabular cup, acetabular shell, acetabular liner, bipolar head, dual mobility cup |
| **Classification Names:** | LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented;<br>LPH – prosthesis, hip, semi-constrained, metal/polymer, porous uncemented<br>OQI – hip, semi-constrained, cemented, metal/ceramic/polymer + additive, porous uncemented<br>MEH - Prosthesis, hip, semi-constrained, uncemented, metal / polymer, non-porous, calcium phosphate;<br>JDI - Prosthesis, hip, semi-constrained, metal/polymer, cemented;<br>KWL - Prosthesis, hip, femoral component, cemented, metal; |

| | |
|---|---|
| | KWY - Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented;<br>OQG – hip prosthesis, semi-constrained, cemented, metal/polymer, + additive, porous, uncemented;<br>MBL - prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous. |
| **Classification Codes:** | LZO, LPH, OQI, MEH, KWL, KWY, JDI, OQG, MBL, all class II |
| **Classification Panel:** | Orthopaedic |
| **Regulation Numbers:** | 21 CFR 888.3353, 888.3358, 888.3390, 888.3350, 888.3360 |

**C. PREDICATE DEVICES**

| | |
|---|---|
| K093472, K110087, K111481, K122305, K123705, K130128, K130343, K131647 | Primary Predicate Device:<br>Corin Trinity Acetabular System, including acetabular shells of various configurations, femoral heads, bone screws, hole occluders, and HXLPE and ecima acetabular liners |
| | Secondary Predicate Devices: |
| K093472, K110087, K130343, K131647 | Corin CoCrMo femoral heads, various diameters and offsets |
| K172551 | Corin PLUS Acetabular Shell |
| K082525, K120362, K121439, K153381 | Corin MetaFix Hip System |
| K173880 | Corin TriFit CF Hip System |
| K121563, K153772 | Corin TriFit TS Hip System |
| K992234, K003666, K142761, K153725 | Corin TaperFit Hip System |
| K152903, K191374 | Corin Revival Modular Hip System |
| K083312, K111046, K131986 | Corin MiniHip |
| K103120 | Corin Biolox Delta femoral heads |
| K170359 | Corin Trinity Dual Mobility System |
| K191831 | Corin MobiliT Cup |
| K183114 | Corin BiPolar-i |
| K000788 | OMNI MOD Hip System (formerly Apex) |
| K041950 | OMNI K2 Hip System (formerly Apex, now OMNI MOD) |
| K060072, K110947 | OMNI K1 Hip System |
| K101451 | OMNI Delta Ceramic Head (originally trade named Apex) |
| K082468, K100151 | OMNI Hip System Bipolar Head |

## D. DEVICE DESCRIPTION

The subject and predicate devices are one in the same and are comprised of several legally marketed Corin Ltd. hip products, which include OMNIlife Sciences and Apex Surgical hip products. The subject devices include acetabular cups and liners, bone fixation screws, screw hole occluders, cemented and cementless femoral hip stems for primary and revision hip arthroplasty, fixation screws, modular necks, CoCrMo alloy and ceramic femoral heads, dual mobility acetabular systems, and bipolar heads. The purpose of this 510(k) is to notify the FDA of Corin's engineering assessment of the cross-compatibility of the subject devices, identification of conflicts, and updates to the product labeling.

The subject hip devices components are manufactured from a variety of materials which include cobalt-chromium-molybdenum alloy, stainless steel alloy, titanium alloy, unalloyed titanium, calcium phosphate (Bonit™ coating) Alumina Matrix Composite ceramic (Biolox Delta), and ultrahigh molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards, or internal standards. The subject femoral hip stems and heads possess the same 12/14 taper design and reference system for determining head and neck offsets.

## E. INTENDED USE

The Corin Ltd. hip products are single use only devices. The indications for use for the predicate and subject devices are the same as provided in the table below.

| 510(k) number(s)<br>Product name | Indications for Use |
|---|---|
| K093472, K110087, K111481, K122305, K123705, K130128, K130343, K131647<br>Corin Trinity™ Acetabular System<br>Including CoCrMo femoral heads in K093472, K110087, K130343, K131647 | The indications for the Trinity™ Acetabular System 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), and congenital dysplasia of the hip (CDH). The Trinity Acetabular System is intended for cementless use only. |
| K172551<br>Corin Trinity™ PLUS Acetabular Shell | 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. |
| K082525, K120362, K121439, K153381<br>Corin MetaFix™ Hip | The indications for the Corin MetaFix™ Hip Stem as a total hip arthroplasty, and when used in combination with a Corin hemi arthroplasty head, as a hip hemi-arthroplasty, 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) and congenital dysplasia of the hip (CDH). The Corin Metafix Hip Stem is indicated for cementless use only. |

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| K173880<br>Corin TriFit CF™ Hip | The indications for the Corin TriFit™ CF Hip Stem as a total hip arthroplasty and 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 of the proximal femur; Developmental Dysplasia of the Hip (DDH); Previously failed hip surgery. The Corin TriFit™ CF Hip Stem is indicated for cementless use only. |
| K121563, K153772,<br><br>Corin TriFit TS™ Hip | The indications for the Corin TriFit TS™ Hip as a total hip arthroplasty, and when used in combination with a Corin hemi arthroplasty head, as a hip hemi-arthroplasty, include: Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, Rheumatoid arthritis, Correction of functional deformity, Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur, Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH). The TriFit TS Hip is intended for cementless use only. |
| K992234, K003666, K142761, K153725<br>Corin TaperFit™ | TaperFit™ Hip Stem is indicated for the relief of pain and restoration of hip function following the effects of osteo, rheumatoid and inflammatory arthritis, post-traumatic disease effects, avascular necrosis and total hip revision. The TaperFit Hip Stem is indicated for hemi-arthroplasty when used in combination with Corin hemi-arthroplasty femoral heads. The TaperFit Hip Stem is indicated for cemented, single use only. |
| K152903, K191374<br>Corin Revival™<br>Modular Hip Stem | The Revival™ Modular Revision Hip Stem is indicated in revision surgery of femoral components, following failure of primary cemented or un-cemented prosthesis. The REVIVAL™ Modular Hip Stem 100mm distal component is also indicated in primary total hip arthroplasty. The indications for the Revival ™ Modular Revision Hip Stem include: Non-inflammatory degenerative joint disease including primary and secondary osteoarthritis and hip dysplasia, Aseptic necrosis of the femoral head, Rheumatoid arthritis, Correction of functional deformity, Treatment of non-union and femoral neck fractures, Treatment of traumatic dislocations of the hip, Failures of osteotomy, Treatment of arthrodesis. The Revival ™ Modular Revision Hip Stem is indicated for cementless, single use only. |
| K083312, K111046, K131986<br>Corin MiniHip™ Stem | The indications for the MiniHip™ Stem 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) and congenital dysplasia of the hip (CDH), The MiniHip Stem is indicated for cementless use only. |
| K103120<br>Corin BIOLOX™ delta | The Trinity™ Acetabular System is indicated for use in non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, correction of functional deformity, developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH). The Trinity Acetabular System is intended for cementless, single use only. |
| K170359<br>Corin Trinity™ Dual Mobility | The Trinity™ Dual Mobility System is intended for use in the following indications: 1. Non-inflammatory degenerative joint disease, including osteoarthritis & avascular necrosis 2. Rheumatoid Arthritis 3. Correction of functional deformity 4. Revision of previously failed total hip arthroplasty 5. Patients at increased risk of dislocation 6. Developmental dysplasia of the hip (DDH). The Trinity™ Dual Mobility System is indicated for cementless use only. |
| K191831<br>MobiliT™ Cup | The MobiliT™ Cup, for cemented and cementless use, are indicated for primary replacement of the hip joint:- In degenerative pathologies: primary, secondary or post-traumatic osteoarthritis, rheumatoid arthritis- For patients who have a high risk of dislocation- In cases of necrosis of the femoral head- In cases of |

| | |
|---|---|
| | fracture of the neck of the femur- In cases of congenital luxation. The MobiliT™ Cup, for cemented and cementless use, are indicated for revision when the bone tissue remains sufficient after the removal of the previous acetabular cup. The cementless MobiliT™ standard Cup, with flanges or with flanges and hook are indicated for cementless use only. The cemented MobiliT™ Cup is indicated for cemented use only. |
| K183114<br>Corin BiPolar-i | The BiPolar-i is intended for use in the following indications: Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis in which the acetabulum does not require replacement, Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur, Revision of failed partial hip replacements in which the acetabulum does not require replacement. The BiPolar-i is indicated for cementless use only. |
| K000788<br>OMNI MOD™ Hip System was formerly the Apex Modular hip<br>Including CoCrMo femoral heads | The indications for use of the OMNI Modular Hip Stems in hip arthroplasty include the following conditions; as appropriate: Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis; Rheumatoid arthritis; Correction of functional deformity; Congenital dislocation; Revision procedures where other treatments or devices have failed; Femoral neck and trochanteric fractures of the proximal femur.<br>The OMNI modular hip stems are indicated for cementless use only and single use implantation. |
| K041950<br>OMNI K2 Hip was originally Apex K2 hip<br>OMNI Modular Hip was originally Apex Modular hip system<br>Both stems trade named OMNI | The indications for use of the OMNI Modular Hip Stems in hip arthroplasty include the following conditions, as appropriate: Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis; Rheumatoid arthritis; Correction of functional deformity; Congenital dislocation; Revision procedures where other treatments or devices have failed; Femoral neck and trochanteric fractures of the proximal femur.<br>The OMNI Modular Hip stems are indicated for cementless use only and single use implantation |
| K060072, K110947<br>OMNI K1 Hip System | The indications for use of the K1 Hip Stem in hip arthroplasty include the following conditions, as appropriate: Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis; Rheumatoid arthritis; Correction of functional deformity; Congenital dislocation; Revision procedures where other treatments or devices have failed; Femoral neck and trochanteric fractures of the proximal femur. The K1 Hip Stem is indicated for cementless use only and single use implantation. |
| K101451<br>OMNI Delta Ceramic Femoral Head<br>(originally trade named Apex) | The OMNI Hip system Ceramic Femoral Heads are intended for use in combination with the OMNI Hip System Stems as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with OMNI Interface Acetabular System or bipolar component. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate: Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis, Rheumatoid arthritis, Correction of functional deformity, Congenital dislocation. Revision procedures where other treatments or devices have failed, Femoral neck and trochanteric fractures of the proximal femur. |
| K082468, K100151<br>OMNI Bipolar Head | The Apex Hip System Bipolar Head is intended for use in combination with an Apex Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate: Femoral neck and trochanteric fractures of the proximal femur, Osteonecrosis of the femoral head, Revision procedures where other devices or treatments for these indications have failed. |

## F. TECHNOLOGICAL CHARACTERISTICS

The subject hip devices are indicated for use in primary and revision hip surgery, hemiarthroplasty, and total hip replacement, and are offered in various sizes, materials, and configurations to accommodate patient anatomy, clinical condition, and surgeon preference. The indications for use for the subject devices are provided in the table above, and are the same as the predicate devices. The devices are unchanged except for updates to the labeling of the devices where engineering analysis indicated conflict relative to cross compatibility with other subject devices. Corin engineering analyses established cross compatibility of the subject devices, with the few exceptions noted in the products' labeling.

## G. PERFORMANCE DATA

The performance characteristics of the subject devices were evaluated via engineering analyses to determine cross compatibility with each another. Assessment of product compatibility included the Corin and OMNI (and legacy Apex) modular heads, femoral stems, bone screws, and acetabular systems that are listed in Section C above. The compatibility assessment accounted for materials, geometry, design, and surface finish. More specifically, the subject devices were assessed for cross compatibility as follows:

- OMNI ARC hip stems, OMNI MOD hip stems and modular necks, OMNI K2 hip stems (standard and mid length) and modular necks, and OMNI K1 hip stems, *To be indicated with*: Corin Trinity Heads or OMNI Heads, Corin Trinity Acetabular system and cancellous bone screws, Corin Trinity Dual Mobility Acetabular system, Corin Dual Mobili-T Acetabular system, and Corin Bipolar-i.
- Corin MiniHip hip stems, Corin Revival hip stems, Corin TriFit (TS and CF) hip stems, Corin Taper Fit stems, Corin Metafix stems, *To be indicated with*: Corin Trinity Heads or OMNI Bipolar.

Drawing and CAD analyses were performed to identify differences between the specifications of modular head and stem taper designs for identification of potential conflicts (if any) on the safety and efficacy of the devices when used together. Performance testing was provided along with engineering analyses to leverage predicate testing results. Performance characteristics that were assessed for 'worst case' product type and size included the following:

- Ceramic head burst testing (ISO 7206-10).
- Head pull off and torque off testing (ISO 7206-10).
- Fretting-corrosion testing (ASTM F1875).
- Impingement testing of stem-cup combinations (ASTM F2582).
- Bi-polar head Lever-out and pullout testing.
- Comparison of Corin and OMNI male stem taper geometry and technical specification.
- Comparison of Corin and OMNI female modular head taper technical specifications.
- Comparison of Corin and OMNI CeramTec delta ceramic head drawings and offsets.
- Range of Motion assessment(ISO 21535) of OMNI stems with Corin acetabular systems.
- Assessment of interference for Corin modular heads assembled with OMNI femoral stems.
- Review of materials used for Corin and OMNI heads and stems.

- Comparison of Corin and OMNI stem trunnion and head taper engagement lengths.
- Engineering assessment of fatigue strength of hip stems for Corin and OMNI heads used with OMNI and Corin hip stems, and vice versa.
- An engineering review comparing the cancellous bone screws from OMNI and Corin.
- An engineering analysis to determine the effects of minimum diameter, worst-case congruency of the CoCr femoral heads with the Interface cup UHMWPE liners, on the contact areas, contact stresses, and wear potential at the head-liner interface.

**H. CONCLUSION**

The bench testing, engineering analyses, and labeling presented in this 510(k) notification have established substantial equivalence of the subject and predicate Corin, OMNI, and Apex hip devices, including cross compatibility of use per the products' labeling.