K123705

FEB 12 2013

3. 510(K) SUMMARY

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

2. Contact Person: Diana L. Martone, MS
Regulatory Affairs Associate
Corin USA
813-977-4469
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3. Proprietary Name: Trinity Non-occluded Titanium Plasma Sprayed (TPS) Acetabular Shells

4. Common Name: Hip Prosthesis

5. Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)
Product Codes: LZO, MEH

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   a. Corin Trinity Acetabular System (K093472)
   b. Corin Trinity Acetabular System with HXLPE (K110087)
   c. Corin Trinity Acetabular System with Trinity-i Acetabular Shells (K122305)
   d. United U2 Acetabular Component (K050262)

7. Device Description:

The Trinity Acetabular System is a modular acetabular cup system consisting of a press fit, titanium alloy shell with ultra high molecular weight polyethylene (UHMWPE), highly cross-linked polyethylene (HXLPE) and vitamin E highly cross-linked polyethylene (ECiMa) acetabular liners in neutral offset, +4mm offset, +4mm oblique and neutral 4mm EPW. The Trinity system also includes BIOLOX *delta*™ ceramic and CoCr modular heads which are intended for use with Corin titanium femoral stems. The acetabular shell comes in two variants, a standard Trinity (K093472 and K110087) and a Trinity–i (K122305) shell, both coated with a rough titanium plasma spray with an additional top layer of electrochemically deposited

calcium phosphate (Bonit™). The Trinity and Trinity-i acetabular shells are provided with screw holes and come assembled with titanium occluders in place. Dedicated titanium screws are also provided for additional fixation if required.

The purpose of this submission is to add two more acetabular shell variants to the Trinity Acetabular System, the standard Trinity Non-occluded Titanium Plasma Sprayed (TPS) acetabular shell and the Trinity-i Non-occluded Titanium Plasma Sprayed (TPS) acetabular shell. Both of these variants, subject of this submission, are coated with a rough titanium plasma spray, contain non-threaded holes for the use of titanium screw fixation and do not come pre-assembled with the hole occluders in place.

8. Intended Use / Indications:

The Trinity Acetabular System is intended for use in 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 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) or congenital dysplasia of the hip (CDH)

The Trinity Acetabular System is indicated for cementless, single use only.

9. Summary of Technologies/Substantial Equivalence:

The standard Trinity Non-occluded TPS shell is identical to the standard Trinity Acetabular Shell cleared in K093472 and K110087 in terms of intended use, indications for use, substrate materials, and size range. Likewise, the Trinity-i Non-occluded TPS shell is identical to the Trinity-i Acetabular Shell cleared in K122305 in terms of intended use, indications for use, substrate materials, and size range. The standard Trinity Non-occluded TPS and the Trinity-i Non-occluded TPS shells are similar in design to the Corin predicates with non-threaded holes for the use of titanium screw fixation and a rough titanium plasma spray coating only. The titanium plasma spray coating of the non-occluded TPS variants, subject of this submission, is similar to the titanium plasma spray coating of the United U2

Acetabular Component (K050262) and identical to the titanium plasma spray coating applied to predicates K093472, K110087, and K122305. Based on these similarities, the additional variants subject of this submission, are determined to be substantially equivalent to the predicate devices.

10. Non-Clinical Testing:

Non-clinical testing conducted to demonstrate substantial equivalence includes: screw range of motion and bench testing of the Trinity titanium shells and characterization and testing for the coating which were included in previous submissions for the Corin standard Trinity Acetabular Shells (K093472 and K110087) and the Trinity-i Acetabular Shells (K122305).

The results of this testing show that the Trinity and Trinity-i non-occluded TPS variants are expected to be safe and effective for the proposed indications and are substantially equivalent to the predicate devices.

11. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Corin USA
% Ms. Diana L. Martone
Regulatory Affairs Associate
5670 W. Cypress Street, Suite C
Tampa, Florida 33607

Letter dated: February 12, 2013

Re: K123705
Trade/Device Name: Trinity Acetabular System
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
Dated: November 30, 2012
Received: December 3, 2012

Dear Ms. Martone:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

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): K123705

Device Name: Trinity Acetabular System

Indications for Use:

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
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The Trinity Acetabular System is indicated for cementless, 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)

Michael C. Owens

Division of Orthopedic Devices