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3. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.:

MAR - 9 2011

2. Contact Person: Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate
Corin USA
813-977-4469
lucinda.gerber@coringroup.com

3. Proprietary Name: Trinity Acetabular System

4. Common Name: Hip Prosthesis

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

6. Legally Marketed Devices to which Substantial Equivalence is claimed:
   - Corin Trinity Acetabular System (K093472)
   - Corin Metafix Femoral Stem (K082525)
   - Corin MiniHip Femoral Stem (K083312)

7. Device Description:

The Trinity Acetabular System is a modular acetabular cup system consisting of a press fit, titanium alloy shell (48mm through 68mm in 2mm increments) for use with ultra high molecular weight polyethylene (UHMWPE) liners (28mm and 32mm inner diameters in neutral, +4mm offset, EPW and 10° hooded designs) and a dedicated range of 28mm and 32mm modular 12/14 taper femoral heads providing ceramic (i.e., zirconia and Biolox delta in the USA) or metal on UHMWPE articulation for use in total hip replacement procedures using Corin titanium femoral stems with a 12/14 taper connection. The acetabular shell is coated with a rough titanium plasma spray with an additional top layer of electrochemically deposited calcium phosphate (Bonit™). The acetabular shell is provided with screw holes permitting the use of dedicated titanium bone screws to provide additional fixation if required. Titanium occluders are provided to occlude unused screw holes and an apical introducer hole.

The purpose of this submission is to modify the labeling for the Trinity Acetabular System to include additional Corin titanium femoral stems with a 12/14 taper connection as compatible components, intended for use with the Trinity Acetabular Cup and Liner and the Trinity CoCr Femoral Heads.

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.

8. Intended Use / Indications:

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 intended for cementless use only.

9. Summary of Technologies/Substantial Equivalence:

The additional, compatible Corin titanium femoral stems with a 12/14 taper connection have the same intended use and material and similar indications and designs as the Tri-Fit femoral stems that were previously cleared for use with the Trinity Acetabular System. Based on these similarities, the Trinity Acetabular System with modified labeling is believed to be substantially equivalent to the previously cleared Trinity Acetabular System.

10. Non-Clinical Testing:

A comparison of materials, designs and taper characteristics between the additional, compatible Corin titanium femoral stems with a 12/14 taper connection and the Corin Tri-Fit femoral stems was conducted to demonstrate substantial equivalence of the Trinity Acetabular System, labeled for use with the additional femoral stems, to the previously cleared Trinity Acetabular System. In addition, a range of motion study was conducted to show that the ranges of motion achieved with the additional femoral stems are equivalent to or greater than those achieved with the Tri-Fit femoral stems.

11. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Trinity Acetabular System with modified labeling to the originally cleared Trinity Acetabular System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Corin U.S.A.
% Lucinda Gerber, BA (Hons)
Regulatory Affairs Associate
10500 University Center Dr., Suite 190
Tampa, Florida 33612

MAR - 9 2011

Re: K103518
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: MEH, LZO, LWJ
Dated: February 2, 2011
Received: February 3, 2011

Dear Ms. Gerber:

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

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,

For Peter D Pronovost MD MPH
Deputy Director for Clinical Science
DSORD

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K103518(pg1/1)

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
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Trinity Acetabular System is intended for cementless 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)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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