K111481

FEB - 6 2012

3. 510(K) SUMMARY

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

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

3. Date: 24 January, 2012

4. Proprietary Name: Corin Trinity Acetabular System ECIMA Liners

5. Common Name: Hip Prosthesis

6. Product Codes: OQI, LZO, MEH

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

8. Legally Marketed Devices to which Substantial Equivalence is claimed:

- Corin Trinity Acetabular System with HXLPE Acetabular Liners (K110087)

9. Device Description:

The Trinity Acetabular System is a modular acetabular cup system consisting of a press fit, titanium alloy shell, acetabular liners in neutral offset, +4mm offset, +4mm oblique, neutral 4mm EPW, ceramic and Co-Cr modular heads and titanium femoral stems.

The purpose of this submission is to add ECIMA acetabular liners to the Trinity Acetabular System. Corin's ECIMA is a cold irradiated, mechanically annealed, vitamin E blended ultra high molecular weight polyethylene.

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.

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10. 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.

11. Summary of Technologies/Substantial Equivalence:

The additional components of the Trinity Acetabular System are similar to the predicate devices in terms of intended use and indications, materials, sizes, designs and performance. Based on these similarities, the additional components of the Trinity Acetabular System are believed to be substantially equivalent to the predicate devices.

12. Non-Clinical Testing:

Non-clinical testing was performed on ECiMa acetabular liners to determine tensile strength, impact strength, compressive strength, small punch strength, thermal properties, free radical concentration, oxidation resistance, swell ratio, hip simulator wear under normal and abrasive conditions, wear particle characterization, rim impingement, liner push-out, lever-out, and torque-out resistance, GCMS analysis of hexane and IPA extracts, consolidation assessment, fatigue crack propagation, trans-vinylene index, cyclic loading with accelerated ageing and biocompatibility (i.e., genotoxicity, acute systemic toxicity, irritation, sensitization, cytotoxicity and implantation).

13. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the ECIMA liners of the Trinity Acetabular System and the predicate devices.

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 USA
% Ms. Lucinda Gerber
Regulatory Affairs Associate
10500 University Center Drive, Suite 190
Tampa, Florida 33612

FEB - 6 2012

Re: K111481
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: OQI, LZO, MEH
Dated: January 25, 2012
Received: January 26, 2012

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 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
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): K111481

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)

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

510(k) Number K111481