K093472

3. 510(K) SUMMARY

1. Applicant/Sponsor: Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.: 9614209

NOV 2 3 2010

2. Contact Person: Kathy Trier, Ph.D.
VP Clinical and Regulatory Affairs
Corin USA
813-977-4469
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3. Date of Preparation: November 4, 2010

4. Proprietary Name: Trinity Acetabular System

5. Common Name: Hip Prosthesis

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

7. Legally Marketed Devices to which Substantial Equivalence is claimed:
   a. Depuy Pinnacle Acetabular System (K001534)
   b. Depuy Duraloc Option Acetabular Cup System (K040544)
   c. Aesculap BiContact Hip System with μ-Cap® (K043079)
   d. Corin Zyranox Zirconia Ceramic Femoral Heads (K992235)
   e. Corin Taper-Fit Total Hip System (K003666)
   f. Apex Modular Acetabular Cup (K031110)

8. 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 and 10° hooded designs) and a dedicated range of 28mm and 32mm zirconia and cast cobalt chrome alloy modular 12/14 taper femoral heads providing ceramic or metal on UHMWPE articulation for use in total hip replacement procedures using Corin Tri-fit femoral stems with a 12/14 taper connection. The UHMWPE is previously cleared. 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 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.

9. 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) and congenital dysplasia of the hip (CDH)

The Trinity Acetabular System is intended for cementless use only.

10. Summary of Technologies/Substantial Equivalence:

The Trinity Acetabular System is similar to the predicate systems in design and indications. Technological differences included differences in the exterior coating characteristics and retention mechanism when compared with all identified predicates. The subject acetabular system uses subject CoCr heads and previously cleared zirconia femoral heads and previously cleared non-crosslinked UHMWPE material which is gamma sterilized in nitrogen. Based on the material, characterization data, geometry and mechanical testing, the Trinity Acetabular System is substantially equivalent to legally marketed predicates.

11. Non-Clinical Testing:

Non-clinical testing and analysis were provided, including bench testing and coating characterization. Bench testing included retention mechanism testing (push-out, lever-out and torque-out), range of motion analysis, and bone screw testing (torque-out, pull-out, and range of motion). Testing on the previously cleared UHMWPE included oxidative index testing, impingement testing, and wear testing. The plasma

sprayed underlying CPTi coating with designated thickness was tested for porosity, pore size, surface roughness, mechanical strength (static tensile, static shear, shear fatigue) and taper abrasion. The calcium phosphate coating applied by electrochemical deposition to the CPTi coating was characterized per FDA's "510(k) Information needed for Hydroxyapatite Coated Orthopedic Implants." The dual nonporous coating (calcium phosphate coating overlying the CPTi coating) underwent additional porosity, pore size and thickness measurements. Shell stiffness, shell occluder locking strength, fretting/corrosion testing and pull-off testing of the femoral head were also performed.

All of the observed results indicate that the Trinity Acetabular System is substantially equivalent to devices currently marketed. Therefore, the device is as safe, as effective, and performs at least as safely and effectively as legally marketed predicates

12. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between 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
% Kathy Trier, Ph.D.
VP Clinical and Regulatory Affairs
10500 University Center Drive, Suite 190
Tampa, Florida 33612

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Re: K093472
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: November 10, 2010
Received: November 12, 2010

Dear Dr. Trier:

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

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): K093472

Device Name: Trinity Acetabular System

NOV 2 3 2010

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
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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 MXM

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

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