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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.:

FEB 2 8 2011

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

3. Proprietary Name: Corin BIOLOX delta Modular Femoral Heads

4. Common Name: Femoral Head

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:
   - Zyranox Zirconia Ceramic Modular Heads (K992235)
   - Smith & Nephew BIOLOX delta Ceramic Femoral Heads (K100412)

7. Device Description:

BIOLOX delta material is an aluminum oxide / zirconia ceramic composite composed of approximately 75% aluminum oxide and approximately 25% zirconia.

The Corin BIOLOX delta Modular Femoral Heads are available in 28mm and 32mm diameters. The 28mm heads are available with short (-3.5mm), medium (0mm) and long (+3.5mm) offsets. The 32mm heads are available with short (-4.0mm), medium (0mm), long (+4mm) and extra long (+7mm) offsets.

The Corin Biolox Delta heads are compatible with Corin titanium stems (i.e. Tri-Fit, Metafix and MiniHip femoral stems having a 12/14 taper trunnion) and the Trinity acetabular system.

8. Intended Use / Indications:

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity and
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The Corin BIOLOX delta Modular Femoral Heads are intended for single use only.

9. Summary of Technologies/Substantial Equivalence:

The Corin Biolox Delta modular femoral heads have the same types of indications and intended uses as the predicates. The technological characteristics are the same as the predicates. Based on the materials, geometry, mechanical testing and indications for use, the Biolox Delta heads are considered to be substantially equivalent to the predicate devices.

10. Non-Clinical Testing:

Nonclinical testing included burst strength testing on both the 28mm-12/14L and 32mm-12/14XL Biolox delta heads on the Corin titanium taper trunnion to determine the worst case construct. Subsequently, fatigue, post-fatigue burst and pull-off testing were then performed on the worst case construct. The results of the ceramic head testing meet the suggested values in the "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems." The results of the preclinical data provided indicate that the subject system is within the range of legally marketed predicates.

11. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Corin BIOLOX delta Modular Femoral Heads 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
% Lucinda Gerber, BA (Hons)
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Suite 190
Tampa, Florida 33612

FEB 2 8 2011

Re: K103120
Trade/Device Name: Biolox Delta Modular Femoral 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
Dated: February 09, 2011
Received: February 10, 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 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): K103120

Device Name: Corin BIOLOX delta Modular Femoral Heads

Indications for Use:

The Corin BIOLOX delta Modular Femoral Heads are used in combination with femoral hip stems and ultra high molecular weight polyethylene (UHMWPE) acetabular cup liners to reinstate function following the degenerative effects of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
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The Corin BIOLOX delta Modular Femoral Heads are intended for 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)

for M. Melkerson

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

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