K082525

p. 1/2

FEB - 4 2010

3. 510(K) SUMMARY

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

2. Contact Person: Ashlea Bowen, RAC
Regulatory Affairs Associate
Corin USA
813-977-4469
ashlea.bowen@coringroup.com

3. Proprietary Name: Corin Metafix Hip Stem

4. Common Name: Femoral Hip Stem

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

Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)

6. Product Code: LZO, JDI

7. Legally Marketed Devices to which Substantial Equivalence is claimed:
   a. Depuy Orthopaedics Corail AMT Hip System (K042992)

8. Device Description:

The Corin Metafix Hip Stem is a titanium femoral hip stem featuring a 12/14 tapered male trunnion for assembly with modular femoral head components. The stem is manufactured from Titanium ($TiAl_6V_4$) alloy for surgical implant applications, conforming to ASTM F136-2 and is coated with plasma sprayed hydroxyapatite conforming to ASTM F-1185-88. The stem is designed to be used in conjunction with Corin Eurocone CoCr modular femoral heads (K003666) and Corin Zyranox Zirconia Ceramic modular femoral heads (K992235), both of which mate with Corin Cenator Acetabular Cups (K925866). The stem is available in 9 sizes (Size 2 to Size 10), each available in three lateral offsets including standard, lateralized, and Coxa Vara.

9. Intended Use / Indications:

The indications for the Corin Metafix Hip Stem as a total hip arthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur
- DDH/CDH

The Corin Metafix Hip Stem is indicated for cementless use only.

10. Summary of Technologies/Substantial Equivalence:

The Corin Metafix Hip Stem has the same intended use and indications and is manufactured from the same materials as the predicate. Additionally, the Corin Metafix Hip Stem has proximal horizontal grooves, distal vertical grooves and medial calcar grooves that are substantially equivalent to those found on the predicate device, the Depuy Corail AMT Hip System. Based on these similarities, Corin believes that the Metafix Hip Stem is substantially equivalent to the predicate device.

11. Non-Clinical Testing:

Non-clinical testing and analysis included mechanical fatigue testing, static tensile testing and range of motion testing. The results of this testing show that the Corin Metafix Hip Stem is expected to be safe and effective for the proposed indications and is substantially equivalent to the predicate device.

12. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Corin Metafix Hip Stem and the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Corin USA
% Ms. Ashlea Bowen, RAC
Regulatory Affairs Associate
10500 University Center Drive
Suite 190
Tampa, Florida 33612

FEB - 4 2010

Re: K082525
Trade/Device Name: Corin Metafix Hip Stem
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, JDI
Dated: December 17, 2009
Received: December 18, 2009

Dear Ms. Bowen:

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

K082525 p: 1/1

2. INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Corin Metafix Femoral Stem

Indications for Use:

The indications for the Corin Metafix Hip Stem as a total hip arthroplasty include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur
- DDH/CDH

The Corin Metafix Hip Stem is indicated 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 K082525