3. 510(K) SUMMARY

1. **Applicant/Sponsor:** Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.: 1056629

SEP 14 2012

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

3. **Date:** May 14, 2012

4. **Proprietary Name:** Corin Metafix Hip Stem

5. **Common Name:** Hip Prosthesis

6. **Product Codes:** LZO, KWL, KWY, JDI

7. **Classification Name:** Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21CFR 888.3390)

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21CFR 888.3360)

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)

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

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

- Corin Metafix Hip Stem (K082525)
- Corin Metafix Hip Stem with Hemi-Arthroplasty (K120362)

9. 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 (TiAL6V4) alloy for surgical implant applications, conforming to ASTM F136-11 and is coated with plasma sprayed hydroxyapatite conforming to ASTM F-1185-03(2009). The stem is currently available in nine sizes (2-10), each available in three offsets including Standard (135°), Lateralized 135°, and Standard (125°).

The Corin Metafix Hip Stem was originally cleared in K082525. This submission is for one additional stem size, size 1 in two available offsets, Standard (135°) and Lateralized 135°. Like the originally cleared Metafix Stems, the additional stem size features a low profile lateral shoulder, a tapered metaphyseal flare as well as a vertically and horizontally grooved stem, providing for rotational and axial stability.

The indications and compatible components for use with the Corin Metafix size 1 are identical to that of the predicate devices (K082525 & K120362).

10. Intended Use / Indications:

The indications for the Corin Metafix Hip Stem as a total hip arthroplasty and, when used in combination with Corin hemi-arthroplasty femoral heads, as a hemi-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
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

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

11. Summary of Technologies/Substantial Equivalence:

The additional component of the Corin Metafix Hip Stem is similar to the predicate Corin Metafix Hip Stems in terms of design, and is identical in materials, intended use and indications. Based on these similarities, Corin believes that the Metafix Hip Stem is substantially equivalent to the predicate devices.

12. Non-Clinical Testing:

Non-clinical testing and analysis included mechanical fatigue testing of the neck and stem. The results of this testing show that the Corin Metafix Hip size 1 Stem is expected to be safe and effective for the proposed indications and is substantially equivalent to the predicate device.

13. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the additional size of 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 –WO66-G609
Silver Spring, MD 20993-0002

Corin U.S.A.
% Ms. Lucinda Gerber
10500 University Center Drive
Suite 190
Tampa, FL 33612

SEP 19 2012

Re: K121439
Trade/Device Name: Metafix Femoral Hip Stem Size 1
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: LZO, KWL, KWY
Dated: September 7, 2012
Received: September 10, 2012

Dear Ms. Gerber:

This letter corrects our substantially equivalent letter of September 14, 2012.

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 (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.

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.

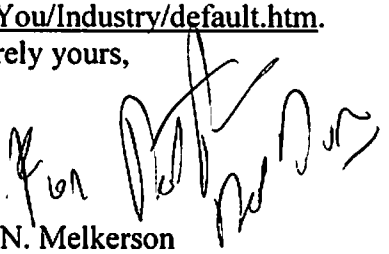
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K121439

Device Name: Corin Metafix Hip Stem

Indications for Use:

The indications for the Corin Metafix Hip Stem as a total hip arthroplasty and, when used in combination with Corin hemi-arthroplasty femoral heads, as a hemi-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
- Developmental dysplasia of the hip (DDH) and congenital dysplasia of the hip (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 K121439

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

510(k) Number K151439