DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 25, 2016

Corin USA Limited
Ms. Diana L. Nader-Martone
Regulatory Affairs Associate
5670 West Cypress Street, Suite C
Tampa, Florida 33607

Re: K153725
Trade/Device Name: Taperfit Hip Stem
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, JDG, KWY
Dated: December 23, 2015
Received: December 28, 2015

Dear Ms. Nader-Martone:

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 Parts 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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 -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153725

Device Name
TaperFit Hip Stem

Indications for Use *(Describe)*
The TaperFit Hip Stem is indicated for the relief of pain and restoration of hip function following the effects of femoral neck fracture, osteo, rheumatoid and inflammatory arthritis, post-traumatic disease effects, avascular necrosis and total hip revision. The TaperFit Hip Stem is indicated for hemi-arthroplasty when used in combination with Corin Bipolar Prosthesis hemi-arthroplasty femoral heads.

The TaperFit Hip Stem is indicated for cemented, single use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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3. 510(K) SUMMARY

1. **Applicant/Sponsor:** Corin USA
   Distributor 5670 W. Cypress Street
   Suite C
   Tampa, Florida 33607
   Establishment Registration No.: 1056629

2. **Contact Person:** Diana L. Nader-Martone
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   Kathy Trier
   VP Global Regulatory and Clinical Affairs
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3. **Date:** March 24, 2016

4. **Proprietary Name:** TaperFit Hip Stem

5. **Common Name:** Hip Prosthesis

6. **Product Code(s):** JDI, JDG, KWY

7. **Classification Name:**
   21CFR 888.3350 – Hip joint metal/polymer semi-constrained cemented prosthesis
   21CFR 888.3390 – Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
   21CFR 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

8. **Legally Marketed Devices to which Substantial Equivalence is claimed:**
   - Corin TaperFit Hip Stem (K142761)
   - Corin Taper-Fit Hip Stem (K992234, K003666)

9. Device Description:

The TaperFit Hip Stem is a highly polished, double tapered, collarless, stainless steel femoral hip stem featuring a 12/14 tapered male trunnion for assembly with modular femoral head components. The stem is manufactured from stainless steel in accordance with ISO 5832-9 - Implants for surgery -- Metallic materials -- Part 9: Wrought high nitrogen stainless steel and is provided with a polymethylmethacrylate (PMMA) Stem Centralizer. The stem is designed to be used in conjunction with Corin Eurocone (E100.XXX cleared in K003666) and Trinity CoCrMo modular femoral heads (E321.XXX cleared in K093472, K110087, K122305, K123705, K130128, K130343 and K131647). The stem is available in sizes, 0 through 4 with 3 offsets 50mm, 45mm, and 38mm, as well as a CDH option with a 36mm offset.

The TaperFit Hip Stem was originally cleared in K142761. This submission is being made to modify the indications for use to include hemi-arthroplasty when used with previously cleared Corin hemi-arthroplasty femoral heads as compatible components. The Corin CoCr Modular 26mm heads (E100.X26) have been cleared as compatible components of the Taper-Fit Hip stem (K003666). The Corin CoCr Modular 26mm heads (E100.X26) are part of the construct of the bipolar heads. Included in this submission is the addition of the Corin Bipolar Femoral Head (K925897) as a compatible component, which is indicated for hemi-arthroplasty.

10. Intended Use / Indications:

The TaperFit Hip Stem is indicated for the relief of pain and restoration of hip function following the effects of femoral neck fracture, osteo, rheumatoid and inflammatory arthritis, post-traumatic disease effects, avascular necrosis and total hip revision. The TaperFit Hip Stem is indicated for hemi-arthroplasty when used in combination with Corin Bipolar Prosthesis hemi-arthroplasty femoral heads.

The TaperFit Hip Stem is indicated for cemented, single use only.

11. Summary of Technologies / Substantial Equivalence:

The TaperFit Hip Stem, subject of this submission, and the predicate TaperFit Hip Stem (K142761) are identical in design, materials, coating, and sizes and similar in terms of intended use/indications for use. Additionally, the TaperFit Hip Stem, subject of this submission, and the predicates, Taper-Fit Hip Stem (K992234 and K003666) are identical in materials, and coating, and similar in terms of design, sizes, and intended use/indications for use. Based on these similarities, Corin believes that the TaperFit Hip Stem is substantially equivalent to the predicate devices.

12. Non-Clinical Testing:

Non-clinical testing and analysis included FEA, mechanical fatigue testing, static tensile testing, rotational torque testing, fretting and corrosion testing, and range of motion testing. This testing was performed and submitted in the previous TaperFit and Taper-Fit Hip Stem submissions (K142761, K992234, and K003666).

13. Clinical Testing:

Clinical testing was not necessary in this Traditional 510(k).