DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2015

Corin USA
Ms. Diana L. Nader-Martone
Regulatory Affairs Associate
5670 W. Cypress Street
Tampa, Florida 33607

Re: K142761
Trade/Device Name: Corin 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
Dated: March 6, 2015
Received: March 9, 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 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 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

2. INDICATIONS FOR USE

510(k) Number (if known): K142761

Device Name: Corin TaperFit Hip Stem

Indications for Use:

TaperFit Hip Stem is indicated for the relief of pain and restoration of hip function following the effects of osteo, rheumatoid and inflammatory arthritis, post-traumatic disease effects, avascular necrosis and total hip revision.

The TaperFit Hip Stem is indicated for cemented, 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)

1. 510(K) SUMMARY

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

2. **Contact Persons:** Diana L. Nader-Martone, MS
Regulatory Affairs Associate
Corin USA
813-977-4469
diana.nader-martone@coringroup.com

Lucinda Gerber, BA (Hons)
US Regulatory and Clinical Affairs Team Leader
Corin USA
813-977-4469
lucinda.gerber@coringroup.com

3. **Date:** September 23, 2014

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

5. **Common Name:** Femoral Hip Stem

6. **Product Codes:** JDI, JDG

7. **Classification Name:**
21CFR 888.3350: Hip joint metal/polymer semi-constrained cemented prosthesis

8. **Legally Marketed Devices to which Substantial Equivalence is claimed:**
- Corin Taper-Fit Hip Stem (K992234, K003666)
- Howmedica / Stryker Exeter Hip Stem (K803126, K891454, K011623, and K110290)
- Trinity Acetabular System (K093472, K110087, K111481, K122305, K123705, K130128, K130343 and K131647)

9. Device Description:

The Corin 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 CoCrMo modular femoral heads (K003666). The stem is currently available in sizes, 1 through 4 with 2 offsets 45mm and 38mm, as well as a CDH option with a 36mm offset.

The purpose of this submission is to add the 1-hole design of the TaperFit Hip Stem to the TaperFit range. This new design has a single rounded elliptical dove-tail hole on the lateral shoulder of the stem for the stem introducer, instead of 2 rounded or angulated introducer holes which the predicate devices have. In addition to the change in introducer hole design, this 510(k) adds size 0 stems to the 38mm and 45mm offsets, and sizes 0 through 4 in a 50mm offset.

The submission is also to modify the labeling for the TaperFit Hip Stem to add the previously cleared Trinity Acetabular System (K093472, K110087, K111481, K122305, K123705, K130128, K130343 and K131647) as compatible components, intended for use with the TaperFit Hip Stem.

10. Intended Use / Indications:

The TaperFit Hip Stem 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.

TaperFit Hip Stem is indicated for the relief of pain and restoration of hip function following the effects of osteo, rheumatoid and inflammatory arthritis, post-traumatic disease effects, avascular necrosis and total hip revision.

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

11. Summary of Technologies/Substantial Equivalence:

The Corin TaperFit Hip Stem, subject of this submission, has the same intended use and indications

and is manufactured from the same materials as the Corin Taper-Fit Hip Stem (K992234 and K003666). Additionally, the Corin TaperFit Hip Stem, the subject device, is similar in design, compatible components and comes in a similar range of sizes as the predicate devices. 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 and range of motion testing. The results of this testing show that the Corin TaperFit Hip Stem with a 1-hole design, and the size 0 stems, are expected to be safe and effective for the proposed indications and are substantially equivalent to the predicate devices.

13. Clinical Testing:

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