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

April 29, 2016

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

Re: K152903
Trade/Device Name: REVIVAL™ Modular Revision 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, MEH
Dated: March 29, 2016
Received: March 30, 2016

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

2. INDICATIONS FOR USE

510(k) Number (if known): K152903

Device Name: REVIVAL™ Modular Revision Hip Stem

Indications for Use:

The REVIVAL™ Modular Revision Hip Stem is indicated in revision surgery of femoral components, following failure of primary cemented or un-cemented prosthesis. The indications for the REVIVAL™ Modular Revision Hip Stem include:

- Non-inflammatory degenerative joint disease including primary and secondary osteoarthritis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union and femoral neck fractures
- Treatment of traumatic dislocations of the hip
- Failures of osteotomy
- Treatment of arthrodesis

The REVIVAL™ Modular Revision Hip Stem is indicated for cementless, 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
   Distributor 5670 W. Cypress Street
   Suite C
   Tampa, Florida 33607
   Establishment Registration No.: 1056629

2. **Manufacturer:** Gruppo Bioimpianti
   Via Liguria, 28
   Peschiera Borromeo (MI)
   Italy
   Establishment Registration No: None

3. **Contact Person:** Diana L. Nader-Martone
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4. **Date:** April 27, 2016

5. **Proprietary Name:** REVIVAL™ Modular Revision Hip Stem

6. **Common Name:** Hip Stem

7. **Product Code(s):** LZO, MEH

8. **Classification Name:** 888.3353 - Hip joint metal/ceramic/ polymer semi-constrained cemented or nonporous uncemented prosthesis

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

- Lima MODULUS stem (K112158)
- Biomet Arcos® Modular Femoral Revision System (K100469, K090757)

10. Device Description:

The REVIVAL™ Modular Revision Hip Stem is a modular stem manufactured from titanium alloy (Ti6 Al 4V ELI) with a proximal component, a distal component and a locking screw. The modular proximal component is available in four lengths (40mm, 50mm, 60mm, and 70mm) and two CCD angles (125˚ and 135˚).The distal component is conical in shape and has longitudinal fins. The distal component design has four lengths (100mm, 160mm, 200mm, and 240mm) and eight diameters (14mm, 16mm, 17mm, 18mm, 19mm, 20mm, 22mm, and 24mm). The proximal and distal components are assembled using a 'Morse' taper 2˚ 51' so that the proximal component can be dialed into position to achieve the anteversion required. The locking screw is used to assemble and hold the 'Morse' taper cone in place. The REVIVAL™ Modular Revision Hip Stem has a surface finish obtained by abrasion with corundum to increase the contact surface for cementless fixation. The device is intended to be used with Corin (12/14 taper) modular heads.

11. Intended Use / Indications:

The REVIVAL™ Modular Revision Hip Stem is indicated in revision surgery of femoral components, following failure of primary cemented or un-cemented prosthesis. The indications for the REVIVAL™ Modular Revision Hip Stem include:

- Non-inflammatory degenerative joint disease including primary and secondary osteoarthritis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union and femoral neck fractures
- Treatment of traumatic dislocations of the hip
- Failures of osteotomy
- Treatment of arthrodesis

The REVIVAL™ Modular Revision Hip Stem is indicated for cementless, single use only.

12. Summary of Technologies/Substantial Equivalence:

The REVIVAL™ Modular Revision Hip Stem is identical to the Biomet Arcos® Modular Femoral Revision System (K100469, K090757) in terms of material. The REVIVAL™ Modular Revision Hip Stem is similar to both the Arcos® and the Lima MODULUS stem (K112158) in indications, component design, and size ranges. All three stems utilize a modular design with a proximal femoral neck component and a distal femoral stem held together with a locking screw. Based

on these similarities, Corin believes that the REVIVAL™ Modular Revision Hip Stem is substantially equivalent to the predicate devices.

13. Non-Clinical Testing:

Non-clinical testing and analysis included finite element analysis (FEA), mechanical fatigue testing, and range of motion testing. Testing also included engineering rationales to demonstrate that the subject device was not a new worst-case for axial disassemble testing, rotational disassemble testing, and ceramic head burst strength testing.

14. Clinical Testing:

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

15. Conclusions:

Based on the results of this testing and the design characteristics of the Corin REVIVAL™ Modular Revision Hip Stem, this device is expected to be safe and effective for the proposed indications and is substantially equivalent to the predicate devices.