July 22, 2019

Corin USA Limited
Rachel King
Senior Regulatory Affairs Associate
12750 Citrus Park Lane
Tampa, Florida 33625

Re: K191374
Trade/Device Name: Revival™ Modular 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: May 22, 2019
Received: May 23, 2019

Dear Rachel King:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Vesa Vuniqi
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K191374

Device Name: Revival™ Modular Hip Stem

Indications for Use:

The Revival™ Modular Hip Stem is indicated in revision surgery of femoral components, following failure of a primary cemented or un-cemented prosthesis. The Revival™ Modular Hip Stem 100mm distal component is also indicated in primary total hip arthroplasty.

The indications for the Revival™ Modular Hip Stem include:

- Non-inflammatory degenerative joint disease including primary and secondary osteoarthritis and hip dysplasia
- Aseptic necrosis of the femoral head
- 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 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)

3. 510(K) SUMMARY

1. Applicant/Sponsor:
Distributor

Corin USA
12750 Citrus Park Lane
Suite 120
Tampa, Florida 33626
Establishment Registration No.: 1056629

2. Manufacturer:

Gruppo Bioimpianti
Via Liguria, 28
Peschiera Borromeo (MI)
Italy
Establishment Registration No: 3007391088

3. Contact Person:

Rachel King
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4. Date: May 22, 2019

5. Proprietary Name: Revival™ Modular 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:

- Revival™ Modular Revision Hip Stem (K152903)
- Lima MODULUS stem (K112158)

10. Device Description:

The Revival™ Modular Hip Stem is a modular stem manufactured from titanium alloy (Ti6Al4V ELI) with a proximal component, a distal component and a locking screw. The modular proximal component is available in four lengths (40, 50, 60, 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 (100, 160, 200, and 240mm) and ten diameters (14, 15, 16, 17, 18, 19, 20, 21, 22, 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 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.

The Revival™ Modular Stem was originally cleared in K152903. This submission is being made to modify the indications for use to include a primary indication and to include additional sizes to the range.

11. Intended Use / Indications:

The Revival™ Modular Revision Hip Stem is indicated in revision surgery of femoral components, following failure of a primary cemented or un-cemented prosthesis. The Revival™ Modular Hip Stem 100mm distal component is also indicated in primary total hip arthroplasty.

The indications for the Revival™ Modular Hip Stem include:

- Non-inflammatory degenerative joint disease including primary and secondary osteoarthritis and hip dysplasia
- Aseptic necrosis of the femoral head
- 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 Hip Stem is indicated for cementless, single use only.

12. Summary of Technologies/Substantial Equivalence:

The Revival™ Modular Hip Stem distal components, subject of this submission, are identical in terms of intended use and indications and material and are similar in terms of design to the predicate Revival™ Modular Revision Hip Stem (K152903). The Revival™ Modular Revision Hip Stem distal components, subject of this submission, are identical in terms of material and similar in terms of design to the predicate Lima MODULUS stem (K112158).

Based on these similarities, Corin believes that the new distal components of the Revival™ Modular Revision Hip Stem are substantially equivalent to the predicate devices.

13. Non-Clinical Testing:

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

Bacterial Endotoxin Testing (BET) has been conducted on finished, sterilized product, using Limulus Amebocyte Lystate (LAL) kinetic chromogenic methodology.

14. Clinical Testing:

Clinical testing was not necessary in this Traditional 510(k) to determine substantial equivalence between the additional components of the Revival™ Modular Hip Stem and the predicate devices.