January 10, 2023

Zimmer GmbH
Nuno Pereira
Regulatory Affairs Specialist
Sulzerallee 8
Winterthur, Zurich 8404
Switzerland

Re: K211047
Trade/Device Name: CoCr Head
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, JDI
Dated: December 9, 2022
Received: December 12, 2022

Dear Nuno Pereira:

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,

Limin Sun -S

Limin Sun, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211047

Device Name
CoCr Head

Indications for Use *(Describe)*

• Noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
• Failed previous surgery where pain, deformity, or dysfunction persists.
• Revision of previously failed hip arthroplasty.

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.

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510 (k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Nuno Pereira Regulatory Affairs Specialist Telephone: +41 76 736 51 91 Fax: +41 52 244 86 58
Date:	December 21, 2022
Trade Name:	CoCr Head
Common Name	Hip Prosthesis
Classification Product Code:	LPH, JDI
Device Classification Name:	Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented
Regulation Number / Description:	21 CFR § 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, LPH 21 CFR § 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis, JDI
Predicate Device:	CoCr Head, manufactured by Zimmer GmbH, K993259, cleared March 10th, 2000
Device Description:	The Subject CoCr Heads are intended to be used as a modular head component for articulation in total hip arthroplasty. A system consisting of a femoral stem, a ball head and a cup or a shell with an insert is used for replacement of the proximal femur in total hip arthroplasty. The articulation is comprised of a modular femoral head and a corresponding cup or acetabular insert. CoCr Heads are to be used in combination with polyethylene cups or inserts. It is also possible to use CoCr Heads in revision cases (unless subsequent to a broken ceramic component) where the stem remains in place. The Subject CoCr Heads have a head diameter of 38 mm and are provided with 5 different neck lengths (from -8 to +8) to allow an individual adaptation of leg length and offset. A 12/14 taper, incorporated in the design of the head, interlocks with the femoral stem. The CoCr Heads are made from Protasul®-20 (CoCrMo alloy).
Indications For Use:	• Noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis. • Failed previous surgery where pain, deformity, or dysfunction persists. • Revision of previously failed hip arthroplasty.
Comparison to Predicate	The materials, design features and sterilization method of the subject

Device:	device remain identical to the predicate device. The subject devices have the same intended use and are substantially equivalent to the legally marketed predicate devices. Minor modifications have been implemented since the last clearance. With this submission, it is proposed to: • establish compatibility of the subject CoCr Heads with the legally marketed Epsilon Durasul Constrained Acetabular Liners. The proposed compatibility extension does not alter the fundamental scientific technology shared by both the subject device and predicate device. • implement MR Conditional labeling for the CoCr Heads. The addition of the MR Conditional labeling does not alter the Indications for Use of the subject devices.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Results from engineering analyses demonstrate that the subject CoCr Heads for which the expansion of product compatibility is proposed remains substantially equivalent to the predicate devices cleared under K993259. This conclusion has been supported by rationales for wear justification, material equivalence (ISO 5834-1, ISO 5834-2, ASTM F648-10, ASTM F2565-06, ASTM F2759-11) and Range of Motion according to ISO 21535. The interactions of Zimmer Hip Joint Replacement implants with static and time varying magnetic fields during Magnetic Resonance Imaging procedures have been evaluated and the subject CoCr Heads have been determined to be MR Conditional in accordance to ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Data and scientific rationalizations to quantify the RF-induced heating, static magnetic field interactions, and image artifact generation of the Zimmer Hip Joint Replacement implants in the 1.5 Tesla (T) and 3.0 T MRI clinically relevant environments have been generated. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.
Conclusion:	The subject devices have the same intended use and similar indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and are manufactured and sterilized using the same materials and processes as the predicate devices. Except for the modifications described in this submission the subject devices are identical to the predicate devices, and the performance data and analyses demonstrate that: • any differences do not raise new questions of safety and effectiveness as established with performance testing; and • the subject devices are at least as safe and effective as the legally marketed predicate devices.