Zimmer GmbH
Gaelle Georges
Regulatory Affairs Senior Specialist
Sulzerallee 8
Winterthur, 8404 Ch

December 26, 2019

Re: K193050
Trade/Device Name: Alloclassic Zweymuller SL Femoral Stem, Alloclassic Zweymuller SL Offset Femoral 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, JDI, KWL, KWY
Dated: October 29, 2019
Received: November 1, 2019

Dear Gaelle Georges:

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

K193050

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Alloclassic® Zweymüller® SL/ SL Offset Femoral Stems

Indications for Use *(Describe)*

Alloclassic® Zweymüller® SL/ SL Offset Femoral Stems:

• 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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K193050

ZIMMER BIOMET

510(k) SUMMARY

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Gaelle Georges Regulatory Affairs Senior Specialist Telephone: +41 58 854 8136 Fax: +41 52 244 86 58
Date:	October 29, 2019
Trade Name:	Alloclassic® Zweymüller® SL Femoral Stem Alloclassic® Zweymüller® SL Offset Femoral Stem
Common Name	Hip Prosthesis
Classification Product Code :	LZO, JDI, KWL, KWY
Device Classification Name:	Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented
Regulation Number / Description:	21 CFR § 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 21 CFR § 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis. 21 CFR § 888.3360 - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis. 21 CFR § 888.3390 - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
Predicate Device:	Alloclassic® Zweymüller® SL Femoral Stem, manufactured by Zimmer GmbH, K962101, first cleared August 19, 1996, subsequently modified by a design change and cleared March 6, 2003 under K030373 Alloclassic® Zweymüller® SL Offset Femoral Stem, manufactured by Zimmer GmbH, K033664, cleared December 17, 2003
Device Description:	The Alloclassic® Zweymüller® SL Femoral Stem is designed as a conical straight stem with a rectangular cross section to ensure rotational stability. The general design of the Alloclassic Zweymüller SL Femoral Stem comprises a slim neck and a short taper. Alloclassic Zweymüller SL Femoral Stems are available in 14 sizes and can be implanted to achieve primary stability in cases of unexpected poor bone quality. Distally the stem is anchored primarily by its edges; proximally the surfaces anchor against the bone cortex. The Alloclassic Zweymüller SL Femoral Stem is manufactured from wrought Ti-Al-Nb titanium alloy

(Protasul-100™, ISO 5832-11 / ASTM 1295-16). The entire stem below the neck of the hip stem is grit basted to provide enhanced bone/prosthesis interface.

The design of Alloclassic® Zweymüller® SL Offset Femoral Stem is very similar to the previously cleared Alloclassic Zweymüller SL Femoral Stems (K962101, K030373), and identical to the previously cleared Alloclassic Zweymüller SL Offset Femoral Stem (K033664). Similar to the Alloclassic Zweymüller SL Femoral Stem, the Alloclassic Zweymüller SL Offset Femoral Stem is a conically shaped straight stem with a rectangular cross section for rotational stability. The entire stem below the neck of the hip stem is grit blasted to provide enhanced bone/prosthesis interface. The stem is available in 14 sizes and is manufactured from the wrought Ti-Al-Nb titanium alloy (Protasul-100™, ISO 5832-11 / ASTM 1295-16). In contrast to the Alloclassic Zweymüller SL Femoral Stem, the Alloclassic Zweymüller SL Offset Femoral Stem provides an additional 6.25 mm of offset (per size) and has a CCD/neck angle of 121° (vs 131° for SL stem). Overall the Alloclassic Zweymüller SL Offset Femoral Stem design provides a higher offset sometimes needed for correcting insufficient soft tissue balancing, restoration of leg length, and sufficient joint stability following total hip arthroplasty.

Indications For Use:

Alloclassic® Zweymüller® SL/ SL Offset Femoral Stems:

- 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 Device:

The intended use and indications for use of the modified devices, as described in its labeling, have not changed as a result of the modifications proposed in the present submission. Further, the materials, design features and sterilization method of the subject devices remain identical to the predicate devices.

Minor modifications have been implemented since the last clearances.

Modification of packaging configuration for the subject implant devices is proposed. The new packaging configuration and the methods to support the package integrity have been previously described in K182048 (Avenir Complete Hip System). The proposed changes do not alter the fundamental scientific technology shared by both the subject devices and predicate devices. In addition, the Instructions For Use (IFU) of the implant devices is proposed to be revised without any changes to the intended use, indications or contraindications: the IFU is being converted to a brand specific IFU and the content is adapted to the subject devices. Zimmer GmbH is furthermore seeking clearance for certain system-specific Class II instruments - these instruments that have previously considered Class I exempt and

	correction of classification to Class II is proposed within present submission.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: *Packaging configuration change:* Packaging performance testing was performed to verify that packaging configuration maintains integrity of the sterile barrier system up to the point of use and provides adequate protection to the product through the hazards of sterilization, handling, distribution and storage according to ISO 11607-1:2006 and ISO 11607-2:2006. Packaging Configuration testing was conducted by representative worst-case products. *Correction of instrument classification from Class I to Class II:* Amendment of Design Controls with verification of mechanical integrity and resistance. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.
Conclusion:	The subject devices have the same intended use and same indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labeling 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.