December 11, 2019

Zimmer GmbH
Tobias Moller
Regulatory Affairs Specialist
Sulzer Allee 8
WINTERTHUR CH 8404

Re: K192236
Trade/Device Name: Fitmore 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, KWL, KWY, KWZ, LWJ, LZO
Dated: October 2, 2019
Received: October 7, 2019

Dear Tobias Moller:

This letter corrects our substantially equivalent letter of November 5, 2019.

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 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,

Vesa Vuniqi -S Date: 2019.12.11 16:53:37 -05'00'

FDA

Vesa Vuniqi
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

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)*
K192236

Device Name
Fitmore® Hip Stem

Indications for Use *(Describe)*
This femoral stem is for total hip or hemi-hip arthroplasty and is indicated for the following conditions:

• Noninflammatory degenerative joint disease (NIDJD), e. g., avascular necrosis, osteoarthritis and inflammatory joint disease (IJD), e. g., rheumatoid arthritis.
• Failed previous hip surgery (not THA) where pain, deformity or dysfunction persists.
• Optional use in revision: in some medical conditions (e. g., early revision when healthy and good bone stock exists) the surgeon may opt to use primary implants in a revision procedure.

This stem is for uncemented use only.

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:	Tobias Möller Specialist, Regulatory Affairs Telephone: +41 58 854 89 94 Fax: +41 52 244 86 58
Date:	October 18, 2019
Trade Name:	Fitmore® Hip Stem
Common or Usual Name:	Hip Prosthesis
Classification Product Code:	JDI, KWL, KWY, KWZ, LWJ, LZO
Device Classification Name:	Prosthesis, Hip, Semi-Constrained (Metal Uncemented Acetabular Component)
Regulation Number / Description:	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 21 CFR § 888.3310 – Hip joint metal/polymer constrained cemented or uncemented prosthesis 21 CFR § 888.3360 – Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR § 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Predicate Device:	Fitmore® Hip Stem, manufactured by Zimmer GmbH, K071723, cleared March 7, 2008
Device Description:	The Fitmore® Hip Stem is a modular femoral stem intended for total or hemi-hip arthroplasty. The component is an uncemented stem which is coated proximally with Titanium Vacuum Plasma Spray and rough-blasted distally for primary stability. The stem design is curved and features a trapezoidal cross-section. The 12/14 femoral stem is available in multiple sizes, consisting of three stem families. The different family designs were developed in order to meet various patients' anatomic needs. As the anatomic offset varies considerably between individuals, the Fitmore® Hip Stem offers a wide range of offset options. Each family is designed with a CCD angle of 140°, 137°, 129° and 127°.

Indications for Use:

This femoral stem is for total hip or hemi-hip arthroplasty and is indicated for the following conditions:

- Noninflammatory degenerative joint disease (NIDJD), e. g., avascular necrosis, osteoarthritis and inflammatory joint disease (IJD), e. g., rheumatoid arthritis.
- Failed previous hip surgery (not THA) where pain, deformity or dysfunction persists.
- Optional use in revision: in some medical conditions (e. g., early revision when healthy and good bone stock exists) the surgeon may opt to use primary implants in a revision procedure.

This stem is for uncemented use only.

Comparison to Predicate Device:

The intended use of the proposed device is identical to those of the previously cleared predicate device. The amount of indications for use have been reduced and reworded for more clarity compared to the previously cleared device. The proposed changes do not alter the fundamental scientific technology shared by both the proposed and predicate devices. Zimmer GmbH is furthermore seeking clearance for minor modifications that have been implemented since the last clearance.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Packaging performance testing was 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 11607-1:2009 and ISO 11607-2:2006. Performance testing further verified that labels and IFU remain intact and legible. Packaging Configuration testing was conducted by representative worst-case products.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion

The subject device has the same intended use and similar indications for use as the predicate device. The subject device uses the same operating principle, incorporates the same basic design and labeling and is manufactured and sterilized using the same materials and processes as the predicate device. Except for the modifications described in this submission the subject device is identical to the predicate device 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.