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

February 7, 2017

Zimmer GmbH
Thomas Lincoln
Senior Regulatory Affairs Specialist
Sulzerallee 8, P.O. Box
8404 Winterthur, Switzerland

Re: K170072
Trade/Device Name: Fitmore Hip Stem
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWY, KWZ, JDI, LZO, LWJ, KWL
Dated: January 3, 2017
Received: January 9, 2017

Dear Thomas Lincoln:

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 Part 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" (21 CFR 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Not yet known (submitted as a Special 510(k) to K071723) K170072

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:

- Non-inflammatory 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.
- Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

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.

510(k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Thomas Lincoln Senior Specialist, Regulatory Affairs Telephone: +41 5885 48 257 Fax: + 41 5224 48 658
Date:	03rd January, 2017
Subject Device:	Trade Name: Fitmore® Hip Stem Common Name: Hip Prosthesis
Classification Product Code / Device Classification Name:	**KWY** – Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented **KWZ** – Prosthesis, hip, constrained, cemented or uncemented, metal/polymer **JDI** – Prosthesis, hip, semiconstrained, metal/polymer, cemented **LZO** – Prosthesis, hip, semiconstrained, metal/ceramic/polymer, cemented or nonporous, uncemented **LWJ** – Prosthesis, hip, semiconstrained, metal polymer, uncemented **KWL** – Prosthesis, hip, hemi-, femoral, metal
Regulation Number / Description:	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 § 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR § 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. 21 CFR § 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

	21 CFR § 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Predicate Device:	Fitmore Hip Stem, manufactured by Zimmer GmbH, K071723, cleared March 7, 2008 (as Zimmer Porolock MIS Stem).
Device Description:	The Fitmore Hip Stem is a modular femoral stem intended for total or hemi-hip arthroplasty. The curved, uncemented stem and is coated proximally with Titanium Vacuum Plasma Sprayed (Ti-VPS) and rough-blasted distally. The 12/14 femoral stem is available in multiple sizes in order to address different patient morphologies. No changes are being made to the Fitmore Hip Stems themselves, a line extension to the rasps provided to facilitate implantation of the Fitmore Hip Stem is being proposed in this submission. The rasps that are subject of this submission are intended to prepare the femoral canal for final implantation of the stem. They are made of Stainless Steel and are sized relative to the intended Fitmore Stem implant beginning with the starter rasp and becoming progressively larger in order that the femoral canal created by the rasps is sized appropriately to the pre-operative templated size of stem with the created canal also providing the required femoral stability
Intended Use:	This femoral stem is for total hip or hemi-hip arthroplasty and is indicated for the following conditions: • Non-inflammatory 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.

- Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

This stem is for uncemented use only.

Comparison to Predicate Device:

The Fitmore Hip Stem implants are not modified as compared to their predicates. The Fitmore Hip Stem implants are identical in intended use, materials, sterility, and performance characteristics to the predicate devices and remain unchanged. Instead, an additional rasp variant is introduced; these rasps are dimensionally larger than the currently available rasps and in all other aspects (intended use, materials, sterility, and performance characteristics) the proposed rasps are identical to the predicate rasps.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical performance testing and analyses demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Performance analyses included:
1. Usability Testing
2. Similar Device Analysis

Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.