



Zimmer GmbH  
Anne-Kathrin Born  
Regulatory Affairs Senior Specialist  
Sulzer Allee 6  
Winterthur, 8404 Ch

April 10, 2020

Re: K200112

Trade/Device Name: Zimmer Hip Joint Replacement

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, LPH, KWZ, JDI, KWL, KWY, LWJ, MEH

Dated: February 6, 2020

Received: February 12, 2020

Dear Anne-Kathrin Born:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

FOR Vesa Vuniqui  
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

## Indications for Use

510(k) Number (if known)  
K200112

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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## Indications for Use

510(k) Number (if known)  
K200112

Device Name  
Avenir® Cemented Hip Stem

### Indications for Use (Describe)

The product is intended for total or hemi hip arthroplasty with cemented applications for rehabilitating hips damaged as a result of:

- Advanced wear of the joint due to degenerative, post-traumatic, or rheumatic diseases
- Failed previous hip surgery including joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty or total hip replacement (THR)
- Acute traumatic fracture of the femoral head or neck
- Avascular necrosis of the femoral head.

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)

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## Indications for Use

510(k) Number (if known)  
K200112

Device Name  
Avenir® Müller Stem

### Indications for Use (Describe)

- Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
- 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.
- Acute traumatic fracture of the femoral head or neck.
- Avascular necrosis of the femoral head.

Avenir® Müller Stems are for cementless 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)

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## Indications for Use

510(k) Number (if known)  
K200112

Device Name  
BIOLOX® delta Ceramic Femoral Head

### Indications for Use (Describe)

The BIOLOX delta Ceramic Femoral Heads are modular components used in total hip arthroplasty and are indicated for the following:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis.
- Patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity.
- Patients with acute femoral neck fractures.

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)

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## Indications for Use

510(k) Number (if known)  
K200112

Device Name  
BIOLOX® OPTION Ceramic Femoral Head System

### Indications for Use (Describe)

The BIOLOX OPTION Ceramic Femoral Head System is comprised of modular components used in primary or revision total hip arthroplasty and is indicated for the following:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis.
- Patients suffering from disability due to previous fusion.
- Patients with previously failed endoprostheses and/or total hip components in the operative extremity.
- Patients with acute neck fractures.

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)

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## Indications for Use

510(k) Number (if known)  
K200112

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)

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## Indications for Use

510(k) Number (if known)  
K200112

Device Name  
Wagner Cone Prosthesis

### 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.
- 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.

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)

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## Indications for Use

510(k) Number (if known)  
K200112

Device Name  
Wagner SL Revision Stem Lateral

Indications for Use (Describe)

- 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)

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## 510(k) Summary

**Sponsor:** Zimmer GmbH  
Sulzerallee 8, P.O. Box  
8404 Winterthur, Switzerland

**Contact Person:** Anne-Kathrin Born, Regulatory Affairs  
Telephone: +41 58 854 86 19  
Fax: + 41 52 244 86 58

**Date:** April 02, 2020

**Trade Name:** *Zimmer Hip Joint Replacement*

**Common Name:** Hip Prosthesis

**Classification Name:** LZO - Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented (21 CFR §888.3353).  
LPH - Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented (21 CFR §888.3358).  
KWZ - Prosthesis, hip, constrained, cemented or uncemented, metal/polymer (21 CFR §888.3310).  
JDI - Prosthesis, hip, semi-constrained, metal/polymer, cemented (21 CFR §888.3350).  
KWL - Prosthesis, hip, hemi-, femoral, metal (21 CFR §888.3360).  
KWY - Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented (21 CFR §888.3390).  
LWJ - Prosthesis, hip, semi-constrained, metal/polymer, uncemented (21 CFR §888.3360).  
MEH - Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium Phosphate (21 CFR §888.3353).

**Predicate Devices:** Wagner SL Revision Stem Lateral, manufactured by Zimmer GmbH, K191781, cleared August 06, 2019  
Wagner Cone Prosthesis System, manufactured by Zimmer GmbH, K191781, cleared August 06, 2019  
Bilox Delta Ceramic Femoral Heads, manufactured by Zimmer GmbH, K192416, cleared October 01, 2019  
Bilox Option Ceramic Femoral Head System, manufactured by Zimmer GmbH, K192416, cleared October 01, 2019  
Fitmore® Hip Stem, manufactured by Zimmer GmbH, K192236, cleared November 5, 2019

Avenir® Cemented Hip Stem, manufactured by Zimmer GmbH, K193030, cleared December 6, 2019

Avenir® Müller Stem, manufactured by Zimmer GmbH, K193030, cleared December 6, 2019

Alloclassic® Zweymüller® SL Femoral Stem, manufactured by Zimmer GmbH, K193050, cleared December 26, 2019

Alloclassic® Zweymüller® SL Offset Femoral Stem, manufactured by Zimmer GmbH, K193050, cleared December 26, 2019

#### Device Description:

Zimmer Hip Joint Replacement Prostheses are hip replacement system components. A femoral stem component is used in conjunction with a femoral head component for replacement of the proximal femur in total hip arthroplasty. Femoral stems are available in different designs, materials, sizes, neck lengths and taper sizes. A taper is incorporated in the design of the stem to interlock it with the femoral head. Femoral head components are available in a variety of sizes and neck lengths for reconstruction of the natural head center of the femur. The purpose of this submission is the addition of MR conditional information to the labeling for the predicate devices. The addition of MR labeling to the subject devices does not impact indications, materials, design features or dimensions of the components, compatibility, packaging, or sterilization.

#### Indications for Use:

**Wagner Cone Prosthesis** are indicated for:

- 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.
- 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.

**Wagner SL Revision Stem Lateral** is indicated for:

- Revision of previously failed hip arthroplasty.

The **BIOLOX delta Ceramic Femoral Heads** are modular components used in total hip arthroplasty and are indicated for the following:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusio acetabuli,

or slipped capital femoral epiphysis.

- Patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity.
- Patients with acute femoral neck fractures.

The **BIOLOX OPTION Ceramic Femoral Head System** is comprised of modular components used in primary or revision total hip arthroplasty and is indicated for the following:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis.
- Patients suffering from disability due to previous fusion.
- Patients with previously failed endoprostheses and/or total hip components in the operative extremity.
- Patients with acute neck fractures.

The **Fitmore® Hip 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.

**Avenir® Müller Stem** is intended for:

- Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
- 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.
- Acute traumatic fracture of the femoral head or neck.
- Avascular necrosis of the femoral head.

Avenir® Müller Stems are for cementless use only.

The **Avenir® Cemented Hip Stem** is intended for total or hemi hip arthroplasty with cemented applications for rehabilitating hips damaged as a result of:

- Advanced wear of the joint due to degenerative, post-traumatic, or rheumatic diseases
- Failed previous hip surgery including joint reconstruction (osteotomy), arthrodesis, hemiarthroplasty or total hip replacement (THR)
- Acute traumatic fracture of the femoral head or neck
- Avascular necrosis of the femoral head.

**Alloclassic® Zweymüller® SL/ SL Offset Femoral Stems** are indicated for:

- 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 subject devices have the same intended use and are substantially equivalent to the legally marketed predicated devices.

**Performance Data (Nonclinical and/or Clinical):**

Non-Clinical Performance and Conclusions:

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 devices 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 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