July 9, 2020

Zimmer, Inc.
Caleb Barylski
Specialist, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46861-0708

Re: K200823
Trade/Device Name: Zimmer, Inc. Hip Joint Prostheses MR Labeling I
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI
Dated: March 27, 2020
Received: March 30, 2020

Dear Caleb Barylski:

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,

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

Enclosure
List of cleared devices in K200823

List of cleared devices in K200823

1. CPT Hip System – MR Conditional
2. Trabecular Metal Primary Hip Prosthesis – MR Conditional
3. Zimmer M/L Taper Hip Prosthesis – MR Conditional
4. ZMR Hip System – MR Conditional
5. Zimmer Biomet Ceramic Heads – MR Conditional
6. Epsilon Acetabular System – MR Conditional
   - Inter-Op HA Porous Acetabular System (HA/CSTi)
   - Inter-Op Acetabular System – Durasul Acetabular Insert
   - Inter-Op Durasul Acetabular Inserts/CoCr Femoral Heads
   - Epsilon Durasul Constrained Acetabular Liner
7. Trabecular Metal Acetabular Revision System Cage – MR Conditional
8. Zimmer Continuum and Trilogy IT Acetabular System – MR Conditional
   - Zimmer Continuum Acetabular System, Zimmer Trilogy IT Acetabular System
   - Longevity IT Highly Crosslinked Polyethylene Elevated Liners
   - Longevity IT Highly Crosslinked Polyethylene Elevated Liners, Continuum Acetabular System and Trilogy Integrated Taper
   - Continuum and Trilogy Integrated Taper (IT) Acetabular Systems; Longevity IT Highly Crosslinked Polyethylene Elevated Liners
   - Vivacit-E Vitamin E Highly Crosslinked Polyethylene Liners
9. Zimmer Continuum and Trilogy IT Longevity IT Constrained Liners – MR Conditional
   - Longevity IT Highly Crosslinked Polyethylene Liners

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)*
K200823

Device Name
Zimmer, Inc. Hip Joint Prostheses MR Labeling I - Epsilon Acetabular System

Indications for Use *(Describe)*

• Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, posttraumatic arthritis, or avascular necrosis and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis
• Those patients with 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K200823

Device Name
Zimmer, Inc. Hip Joint Prostheses MR Labeling I - Epsilon Acetabular System Constrained

Indications for Use *(Describe)*
Primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered. The fixation method of the acetabular components with which this device is intended to be used is porous cementless with supplemental screws, and the fixation method of the femoral components with which this device is intended to be used is cemented, porous cementless, or non-porous cementless fixation, as indicated for use by each respective femoral component.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K200823

Device Name
Zimmer, Inc. Hip Joint Prostheses MR Labeling I - Trabecular Metal Acetabular Revision System Cage

Indications for Use *(Describe)*
This device is indicated for patients with conditions of, but not limited to:
• Acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery.
• Advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis.
• Failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K200823

Device Name

Zimmer, Inc. Hip Joint Prostheses MR Labeling I - Trabecular Metal Primary Hip Prosthesis

Indications for Use *(Describe)*

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K200823

Device Name

Zimmer, Inc. Hip Joint Prostheses MR Labeling I - Zimmer Continuum and Trilogy IT Acetabular System

Indications for Use *(Describe)*

The system is indicated for primary or revision surgery in skeletally mature individuals for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

The system is intended for use either with or without bone cement in total 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K200823

Device Name
Zimmer, Inc. Hip Joint Prostheses MR Labeling I - Zimmer Continuum and Trilogy IT Longevity IT Constrained Liners

Indications for Use *(Describe)*
The Longevity IT Constrained Liner is indicated as a component of a total hip prosthesis in primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K200823

Device Name
Zimmer, Inc. Hip Joint Prostheses MR Labeling I - ZMR Hip System

Indications for Use *(Describe)*
The ZMR Hip System is indicated for cementless revision hip arthroplasty. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief or when there is progressive disability.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K200823

Device Name

Zimmer, Inc. Hip Joint Prostheses MR Labeling I - CPT Hip System

Indications for Use *(Describe)*

The CPT Hip System is indicated for cemented use in:
– 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 affected 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K200823

Device Name
Zimmer, Inc. Hip Joint Prostheses MR Labeling I - Zimmer Biomet Ceramic Heads

Indications for Use *(Describe)*

The Zimmer Biomet Ceramic Heads are indicated for the following conditions: (1) a severely painful and/or disabled hip joint as a result of osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia, (2) avascular necrosis of the femoral head, (3) acute traumatic fracture of the femoral head or neck, (4) failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement, (5) certain cases of ankylosis, (6) nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

When used with constrained acetabular liners, the Zimmer Biomet Ceramic Heads are intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K200823

Device Name
Zimmer, Inc. Hip Joint Prostheses MR Labeling I - Zimmer M/L Taper Hip Prosthesis

Indications for Use *(Describe)*

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

The M/L Taper femoral stem is 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Zimmer, Inc. Hip Joint Prosthesis MR Labeling I 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s,' issued on September 13, 2019.	
Manufacturer/Submitter	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person	Name: Caleb Barylski Phone: 574-371-0250 Email: Caleb.Barylski@zimmerbiomet.com
Date Prepared	July 9, 2020
Subject Device	Trade Name: Zimmer, Inc. Hip Joint Prostheses MR Labeling I Common Name: Hip Prosthesis Class: II Product Codes/Regulation Description: JDI - Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350) KWY - Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR 888.3390) KWZ - Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310) LPH - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358) LWJ - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR 888.3360) LZO - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353) OQG - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358) OQH - Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350) OQI - Hip joint metal/ceramic/polymer semi-constrained cemented

	or nonporous uncemented prosthesis (21 CFR 888.3353)
Predicate Device(s)	**Primary Predicate:** CPT Hip System (K191735, 03/20/2020) **Secondary Predicates:** **<u>Femoral Stems</u>** Trabecular Metal Primary Hip Prosthesis (K051491, 06/30/2005) Zimmer M/L Taper Hip Prosthesis (K192660, 02/28/2020) ZMR Hip System (K113296, 09/14/2012) **<u>Femoral Heads</u>** Zimmer Biomet Ceramic Heads (K181171, 04/02/2019) **<u>Acetabular Components</u>** Epsilon Acetabular System • Inter-Op HA Porous Acetabular System (HA/CSTi) (K972393, 09/19/1997) • Inter-Op Acetabular System – Durasul Acetabular Insert (K983509, 02/03/1999) • Inter-Op Durasul Acetabular Inserts/CoCr Femoral Heads (K993259, 03/10/2000) • Epsilon Durasul Constrained Acetabular Liner (K030923, 10/03/2003) Trabecular Metal Acetabular Revision System Cage (K061226, 08/02/2006) Zimmer Continuum and Trilogy IT Acetabular System • Zimmer Continuum Acetabular System, Zimmer Trilogy IT Acetabular System (K091508, 09/11/2009) • Longevity IT Highly Crosslinked Polyethylene Elevated Liners (K093846, 02/04/2010) • Longevity IT Highly Crosslinked Polyethylene Elevated Liners, Continuum Acetabular System and Trilogy Integrated Taper (K101229, 12/03/2010) • Continuum and Trilogy Integrated Taper (IT) Acetabular Systems; Longevity IT Highly Crosslinked Polyethylene Elevated Liners (K103662, 04/15/2011) • Vivacit-E Vitamin E Highly Crosslinked Polyethylene Liners (K120370, 06/04/2012) Zimmer Continuum and Trilogy IT Longevity IT Constrained Liners • Longevity IT Highly Crosslinked Polyethylene Liners (K101730, 12/03/2010)

	Reference: Zimmer M/L Taper Hip Prosthesis With Kinectiv Technology MR Labeling (K182678, 05/31/2019)
Device Description	Zimmer Hip Joint Prostheses are hip replacement system components. The devices are modular and consist of femoral stems, femoral heads, acetabular shells, acetabular liners, and other ancillary components. The purpose of this submission is the addition of MR conditional labeling to the IFU and device package label of the subject 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	**CPT Hip System** The CPT Hip System is indicated for cemented use in: – 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 affected extremity. – Patients with acute femoral neck fractures. **Epsilon Acetabular System** • Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis, posttraumatic arthritis, or avascular necrosis and inflammatory degenerative joint disease (IJD), e.g., rheumatoid arthritis • Those patients with 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. **Epsilon Acetabular System Constrained** Primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended

	for patients for whom all other options to constrained acetabular components have been considered. The fixation method of the acetabular components with which this device is intended to be used is porous cementless with supplemental screws, and the fixation method of the femoral components with which this device is intended to be used is cemented, porous cementless, or non-porous cementless fixation, as indicated for use by each respective femoral component. **Trabecular Metal Acetabular Revision System Cage** This device is indicated for patients with conditions of, but not limited to: • Acetabular dysplasia, osteoporosis, protrusio acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery. • Advanced joint destruction resulting from degenerative, post-traumatic, or rheumatoid arthritis. • Failed previous surgery, e.g., osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty, or total hip replacement. **Trabecular Metal Primary Hip Prosthesis** Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures. Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected. **Zimmer Biomet Ceramic Heads** The Zimmer Biomet Ceramic Heads are indicated for the following conditions: (1) a severely painful and/or disabled hip joint as a result of osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia, (2) avascular necrosis of the femoral head, (3) acute traumatic fracture of the femoral head or neck, (4) failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or

	total hip replacement, (5) certain cases of ankylosis, (6) nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques. When used with constrained acetabular liners, the Zimmer Biomet Ceramic Heads are intended for primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. **Zimmer Continuum and Trilogy IT Acetabular System** The system is indicated for primary or revision surgery in skeletally mature individuals for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, protrusio acetabuli, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant. The system is intended for use either with or without bone cement in total hip arthroplasty. **Zimmer Continuum and Trilogy IT Longevity IT Constrained Liners** The Longevity IT Constrained Liner is indicated as a component of a total hip prosthesis in primary or revision total hip arthroplasties where there is a high risk of hip dislocation due to a history of instability, bone loss, joint, muscle or tissue laxity, or disease condition. This device is intended for patients for whom all other options to constrained acetabular components have been considered. **Zimmer M/L Taper Hip Prosthesis** Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures. Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted

	femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected. The M/L Taper femoral stem is for cementless use only **<u>ZMR Hip System</u>** The ZMR Hip System is indicated for cementless revision hip arthroplasty. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief or when there is progressive disability.
Summary of Technological Characteristics	The purpose of this submission is to update the Zimmer Hip Joint Replacement Prostheses Instructions for Use precaution section to include MR Conditional labeling along with the addition of the MR Conditional symbol to the device package label. The addition of MR labeling to the subject devices does not impact indications, materials, design features or dimensions, packaging, or sterilization. The subject devices are intended for use in hip arthroplasty.
Summary of Performance Data to Support Substantial Equivalence (Nonclinical and/or Clinical)	**Non-Clinical Tests:** Zimmer has performed non-clinical Magnetic Resonance Imaging (MRI) studies on implants which are 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. MR Tests included the following: • RF-induced heating (ASTM F2182-11a) • Image Artifact (ASTM F2119-07) • Magnetic Displacement (ASTM 2052-14) **Clinical Tests:** • Clinical test data is not provided for the subject device.
Substantial Equivalence Conclusion	Non-clinical tests provided in this Traditional 510(k) establish the conditional safety and compatibility of the passive implants in a magnetic resonance (MR) environment. The subject devices are substantially equivalent to the legally marketed predicated devices.