April 18, 2025

Zimmer Biomet
Sean Gleason
Regulatory Affairs Manager
1800 W. Center Street
Warsaw, Indiana 46580

Re: K250834
Trade/Device Name: Zimmer Biomet Ceramic Heads (22.2mm diameter)
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, KWY, KWZ
Dated: March 19, 2025
Received: March 19, 2025

Dear Sean Gleason:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250834

Please provide the device trade name(s).

Zimmer Biomet Ceramic Heads (22.2mm diameter)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) # K250834:

510(k) Summary

Prepared on: 2025-03-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer Biomet
Applicant Address	1800 W. Center Street Warsaw IN 46580 United States
Applicant Contact Telephone	220-219-8092
Applicant Contact	Mr. Sean Gleason
Applicant Contact Email	sean.gleason@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Zimmer Biomet Ceramic Heads (22.2mm diameter)
Common Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Classification Name	Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented
Regulation Number	888.3353
Product Code(s)	LZO, KWY, KWZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181171, K200823	Zimmer Biomet Ceramic Heads	LZO, KWY, KWZ

Device Description Summary

21 CFR 807.92(a)(4)

The subject premarket notification is submitted as a result of changes being effected per the FDA Guidance on When to Submit a 510(k) in order to add a contraindication to the labeling.

The Zimmer Biomet Ceramic Heads are made from a composite ceramic containing approximately 75% alumina (Al_2O_3) and 25% zirconia (ZrO_2) (percentage by weight). They are supplied with a 12/14 bore or a Type 1 bore. The scope of the subject submission is limited to the 22.2mm head diameter with multiple neck configurations.

The subject ceramic heads are intended for mating with Ti-6Al-4V alloy, Ti-6Al-7Nb alloy stems with tapered necks. They may only be used in combination with highly crosslinked or conventional polyethylene (PE) or metal-back polyethylene liners.

A detailed description of the proposed device is presented in Attachment 31 - Comprehensive Device Description and Principles of Operation.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison **21 CFR 807.92(a)(5)**

Indications for Use: Identical
Intended Use: Identical

Technological Comparison **21 CFR 807.92(a)(6)**

The only difference between the subject device and the predicate device is the addition of a contraindication for the use of 22.2mm ceramic heads with stainless steel femoral stems. All technological characteristics of the subject device remain identical to those of the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions **21 CFR 807.92(b)**

No Non-Clinical and/or Clinical Tests were submitted to determine the substantial equivalence of the subject device with the predicate.