April 28, 2022

Zimmer, Inc.
Adam Haas
Regulatory Affairs Senior Specialist
1800 W. Center Street
Warsaw, Indiana 46580

Re: K212512
Trade/Device Name: G7® Vivacit-E® Freedom® Constrained Liner
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip Joint Metal/Polymer Constrained Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: PBI, JDI, KWZ, LPH, LZO, OQG, OQH, OQI
Dated: April 1, 2022
Received: April 1, 2022

Dear Adam Haas:

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,

Limin Sun, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212512

Device Name
G7® Vivacit-E® Freedom® Constrained Liner

Indications for Use *(Describe)*

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques
5) Revision procedures where other treatment or devices have failed

Porous acetabular shells and femoral stems are indicated for uncemented biological fixation. Non-coated or polyethylene components may be used with mating components that are indicated for either cemented or uncemented use.

Indications for G7® Vivacit-E® Freedom® Constrained Liner:

The G7® Vivacit-E® Freedom® Constrained Liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative 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.

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510(k) Summary

Sponsor:

Zimmer, Inc.
1800 W. Center Street
Warsaw, IN 46580
Establishment Registration Number: 1822565

Contact Person:

Adam Haas
Regulatory Affairs Senior Specialist
Telephone: (908-361-7475)
Adam.Haas@zimmerbiomet.com

Date:

April 27, 2022

Subject Device:

Trade Name: *G7 ® Vivacit-E ® Freedom ® Constrained Liner*

Primary Classification Name:

- PBI – Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/Polymer, + Additive (21 CFR 888.3310 – Hip joint metal/polymer constrained cemented or uncemented prosthesis)

Additional Classification Names:

- JDI – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (21 CFR 888.3350 – Hip joint metal/polymer semi-constrained cemented prosthesis)
- KWZ – Prosthesis, Hip, Constrained, Cemented Or Uncemented, Metal/Polymer (21 CFR 888.3310 – Hip joint metal/polymer constrained cemented or uncemented prosthesis)
- LPH – Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis)
- LZO – Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented (21 CFR 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis)

- OQG – Hip Prosthesis, Semi-Constrained, Cemented, Metal/Polymer, + Additive, Porous, Uncemented (21 CFR 888.3358 – Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis)
- OQH – Hip, Semi-Constrained, Cemented, Metal/Polymer + Additive, Cemented (21 CFR 888.3350 – Hip joint metal/polymer semi-constrained cemented prosthesis)
- OQI – Hip, Semi-Constrained, Cemented, Metal/Ceramic/Polymer + Additive, Porous Uncemented (21 CFR 888.3353 – Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis)

Predicate Device(s):

510(k) Number	***Device Name***	***Applicant***
K121874 (primary) and K142882	*G7* E1 ® *Freedom* Constrained Liner	Biomet Orthopedics

Reference Predicate:

510(k) Number	***Device Name***	***Applicant***
K071718	Trilogy Longevity Constrained Liner	Zimmer, Inc.

Device Description:

The *G7* Acetabular System currently offers a constrained Vitamin E infused highly crosslinked ultra high molecular weight polyethylene (UHMWPE) liner, branded *E1* polyethylene, with a preassembled titanium alloy constraining ring. The constrained liner is designed for use in primary or revision total hip arthroplasty (THA) patients that are at a greater risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability.

Zimmer Biomet has designed and developed a new constrained liner for use within the *G7* Acetabular System, the *G7* ® *Vivacit-E* ® *Freedom* ® *Constrained Liner*. The purpose of this submission is to obtain clearance for this new constrained liner.

Indications for Use:

1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques
5) Revision procedures where other treatment or devices have failed

Porous acetabular shells and femoral stems are indicated for uncemented biological fixation. Non-coated or polyethylene components may be used with mating components that are indicated for either cemented or uncemented use.

Indications for *G7® Vivacit-E® Freedom® Constrained Liner*:

The *G7 ® Vivacit-E ® Freedom ® Constrained Liner* is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability, and for whom all other options to constrained acetabular components have been considered.

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** Same as the predicate device.
- **Indications for Use:** Same as the predicate device.
- **Variants/Sizes:** Same as the predicate device.
- **Design Features:** Similar to the predicate device
- **Material:** The constraining ring and plug materials are same as the predicate device. The polyethylene materials used for the subject and the predicate devices are both Vitamin E infused highly crosslinked ultra high molecular weight polyethylenes. The two polyethylene materials use the same resin (GUR1020) but have different concentrations of Vitamin E and different manufacturing processes.
- **Sterility:** Same as the predicate device.
- **Shelf Life:** Same as the predicate device.

Summary of Performance Data (Nonclinical and/or Clinical):

Following performance testing/evaluation were performed for the subject liner and are included in this 510(k) submission –

- Minimum Dynamic Insertion Energy Required to Seat *G7 ® Vivacit-E ® Freedom ® Constrained Liner*
- *G7 ® Vivacit-E ® Freedom ® Constrained Liner* Torque Out Evaluation, *Freedom* Femoral Head Push-in and Pull-out forces from *G7 ® Vivacit-E ® Freedom ® Constrained Liner*
- *Freedom* Femoral Head Lever Out from *G7 ® Vivacit-E ® Freedom ® Constrained Liner*
- Disassembly of the *G7 ® Vivacit-E ® Freedom ® Constrained Liner* Construct via Lever-Out
- Disassembly of the 36mm *G7 ® Vivacit-E ® Freedom ® Constrained Liner* Construct via Lever-Out
- In-Vitro Wear Testing of the *G7 ® Vivacit-E ® Freedom ® Constrained Liner*
- Constraining Ring Disassembly from the *G7 ® Vivacit-E ® Freedom ® Constrained Liner*
- Evaluation of *G7 ® Vivacit-E ® Freedom ® Constrained Liner* in the Magnetic Resonance (MR) Imaging Environment
- Anatomic Fatigue Testing of *G7 ® Vivacit-E ® Freedom ® Constrained Liner*
- Rim Impingement Testing of *G7 ® Vivacit-E ® Freedom ® Constrained Liner*
- *G7 ® Vivacit-E ® Freedom ® Constrained Liner* Range of Motion
- *G7 ® Vivacit-E ® Freedom ® Constrained Liner* Lever-Out Test
- In-Vitro Wear Testing of the *G7 ® Vivacit-E ® Freedom ® Constrained Liners* in the Presence of Abrasive Particles

Substantial Equivalence Conclusion:

The intended use, indications for use, variants, sizes, materials (for the constraining ring and the plug), sterilization method, and shelf life of the subject liner are same as that of the predicate device. There are differences in the design features and material between the subject liner and the predicate device. However, these differences do not

raise new questions of safety and/or effectiveness. The performance testing/evaluation and the biological safety risk assessment included in this 510(k) submission demonstrates that the subject liner is at least as safe and effective as the predicate device. Therefore, it is concluded that the *G7 ® Vivacit-E ® Freedom ® Constrained Liner* is substantially equivalent to the predicate device.