June 6, 2025

Globus Medical, Inc
Jennifer Antonacci
Senior Group Manager, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Ave
Audubon, Pennsylvania 19403

Re: K243456
Trade/Device Name: ONVOY™ Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, MBL, OQG, LZO
Dated: May 9, 2025
Received: May 9, 2025

Dear Jennifer Antonacci:

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,

Limin Sun -S

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

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)*
K243456

Device Name
ONVOY™ Acetabular System

Indications for Use *(Describe)*
The ONVOY Acetabular System is intended for use in reconstruction of the articulating surface of the acetabular portion of the hip that is severely disabled and/or very painful resulting from:

1. Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, 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 using other techniques.
5. Revision of previously failed total hip arthroplasty.
6. Dislocation risks.

The ONVOY Acetabular System is used in conjunction with Globus/StelKast Hip Systems. The acetabular components of this hip system are intended for cementless fixation.

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: ONVOY™ Acetabular System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Jennifer Antonacci, Ph.D.
Director, Regulatory Affairs

Secondary Contact: Amber Thomas
Regulatory Specialist

Date Prepared: June 6, 2025

Device Name: ONVOY™ Acetabular System

Common Name: Hip Prosthesis

Classification: Per 21 CFR as follows:

- §888.3358 Hip joint metal/polymer/metal semiconstrained porous-coated uncemented prosthesis
- §888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Product Codes: LPH, MBL, OQG, LZO
Regulatory Class: II, Panel Code: 87

Primary Predicate: ONVOY™ Acetabular System (K213842)

Additional Predicates:
Smith and Nephew OR3O (K191002)
Zimmer Biomet G7® Dual Mobility System (K150522, K161190)
Zimmer Biomet G7® Acetabular System (K190660)
StelKast EXp Acetabular Liner (K094035)
Stryker Trident X3 (K182468)
Stryker MDM X3 (K103233)
Signature SignaSure Dual Mobility System (K220495)

Reference Devices: HEDRON® Cervical & Lumbar Spacers, SABLE® Expandable Spacer (K222270)

Purpose:
The purpose of this submission is to request clearance for additional ONVOY™ hip implants, including new acetabular shells and liners, dual mobility implants, and femoral heads.

Device Description:
The ONVOY™ additional implants consist of acetabular shells, liners, and dual mobility liners and bearings that are used as part of a complete total hip system in conjunction with a femoral head and femoral stem in total hip arthroplasty. New femoral head sizes are also being introduced. Implants are available in various configurations and sizes to fit a wide variety of patient anatomy. Shells are available in a cluster-hole design, liners are available in hooded, non-hooded, and lateralized designs used in conjunction with ONVOY shells. Dual mobility polyethylene bearings are used with dual mobility liners.

ONVOY™ acetabular shells are additively manufactured from titanium alloy powder per ASTM F3001. Acetabular liners and dual mobility bearings are manufactured from highly crosslinked ultra-high molecular weight polyethylene (UHMWPE) with Vitamin E. Dual mobility liners are manufactured from Cobalt Chrome (CoCr) alloy and femoral heads are manufactured from alumina matrix composite ceramic.

Indications for Use:
The ONVOY Acetabular System is intended for use in reconstruction of the articulating surface of the acetabular portion of the hip that is severely disabled and/or very painful resulting from:

1. Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, 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 using other techniques.
5. Revision of previously failed total hip arthroplasty.
6. Dislocation risks.

The ONVOY Acetabular System is used in conjunction with Globus/StelKast Hip Systems. The acetabular components of this hip system are intended for cementless fixation.

Performance Data:
Mechanical testing (fatigue, axial disassembly, lever-out, torque-out, deformation, wear, impingement, burst, and fretting and corrosion testing) was conducted in accordance with ASTM F3090, ASTM F1820, ASTM F1875, ASTM F2345, ASTM F2582, ISO 7206-12, and ISO 14242. Range of motion (ROM) assessment was conducted in accordance with ISO 21535. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST72:2011. Performance data demonstrate substantial equivalence to the predicate devices.

Technological Characteristics:
Subject ONVOY™ implants have similar technological characteristics as the predicate devices including design (locking mechanism, material thickness, and bearing diameter), intended use, material composition, function, and range of sizes. The subject ONVOY™ shells differ in manufacturing method; the polyethylene liners and dual mobility bearings differ in crosslinking radiation dose as compared to the predicate devices. These differences have been evaluated and do not raise any new concerns of safety or effectiveness for the subject ONVOY™ Acetabular System for its intended indications for use.

Basis of Substantial Equivalence:
Subject ONVOY™ Acetabular System implants have been found to be substantially equivalent to the predicate devices with respect to technological characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject implants to the predicate devices.