Globus Medical Inc.
Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K213842
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
Dated: September 14, 2022
Received: September 14, 2022

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 (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.
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)*
K213842

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.

The ONVOY™ Acetabular System is used in conjunction with Globus/Stelkast hip systems. The acetabular components of this 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.

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.

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"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: ONVOY™ Acetabular System

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

Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: October 3, 2022

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

Primary Predicate: StelKast Cross-Over Acetabular Shell and Liner (K122773)

Additional Predicates:
Smith & Nephew REFLECTION 3 Shell (K070756)
StelKast ProForm Hip System (K950827)
NovoSource NovoHip Total Hip System (K132158)
Zimmer Trilogy Acetabular System (K934765)

Purpose:
The purpose of this submission is to request clearance for new acetabular shells, liners and bone screws.

Device Description:
The ONVOY™ Acetabular System consists of shells, liners, and bone screws that are used as part of a complete total hip system in conjunction with a femoral head and femoral stem in total hip arthroplasty. 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 and non-hooded designs used in conjunction with the shells, and bone screws provide additional fixation when inserted through the shell.

ONVOY™ acetabular shells are manufactured from titanium alloy, with a commercially pure titanium vacuum sintered coating. The liners are manufactured from ultra-high molecular weight polyethylene (UHMWPE) with Vitamin E. Bone screws are manufactured from titanium alloy.

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

Performance Data:
Mechanical testing (push-out, lever-out, and torque-out disassembly, impingement, deformation, screw testing, shell fatigue and range of motion) was conducted in accordance with ASTM F1820, ASTM F2582, ISO 7206-12, ASTM F543, ASTM F3090, and ISO 21535. Performance data demonstrate substantial equivalence to the predicate devices. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

Technological Characteristics:
Subject ONVOY™ implants have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

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