August 4, 2026

Globus Medical, Inc.
Amber Thomas
Regulatory Specialist
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K254043
Trade/Device Name: TRIVANCE™ Hip Stem
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, JDI, LWJ, LZO, OQH, OQI, KWY
Dated: July 2, 2026
Received: July 6, 2026

Dear Amber Thomas:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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)*
K254043

Device Name
TRIVANCE™ Hip Stem

Indications for Use *(Describe)*
The TRIVANCE™ stems are intended for total and hemi-hip arthroplasty in skeletally mature patients for the following indications:

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 TRIVANCE™ stems are intended for cemented and uncemented applications.

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:

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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

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

Primary Contact: Amber Thomas
Regulatory Specialist

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

Date Prepared: August 4, 2026

Device Name: TRIVANCE™ Hip Stem

Common Name: Hip Prosthesis

Classification: Per 21 CFR as follows:

- §888.3358 Hip joint metal/polymer/metal semiconstrained porous-coated uncemented prosthesis
- §888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis
- §888.3353 Hip joint metal /ceramic /polymer semi-constrained cemented or nonporous uncemented prosthesis
- §888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
- §888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis

Product Codes: LPH, JDI, LWJ, LZO, OQH, OQI, KWY
Regulatory Class: II, Panel Code: 87

Primary Predicate: PROVIDENT II (K190276)

Additional Predicates: DePuy Actis (K210581, K202472, K160907, K150862)
StelKast Progeny (K001984)
DePuy C-Stem (K220216, K082239, K982918)

Purpose:
The purpose of this submission is to request clearance for TRIVANCE™ hip stem implants.

Device Description:
The TRIVANCE™ Hip Stem is a femoral prosthesis intended to replace a hip joint. TRIVANCE™ implants include tri-tapered hips stems and distal centralizers.

Implants are available in various sizes to fit a wide variety of patient anatomy. Stems are available in standard and lateralized versions in both press-fit (cementless) and cemented designs. Distal Centralizers in various sizes are used with cemented stems. TRIVANCE™ stems are compatible with existing Globus femoral heads, bi-polar heads, acetabular liners, dual mobility liners, and acetabular shells for use in traditional, dual mobility, and bi-polar hip constructs.

The press-fit stem is manufactured from titanium alloy and is coated with hydroxyapatite and titanium plasma spray. The cemented stem is manufactured from cobalt chrome. The distal centralizer is manufactured from medical grade polymethylmethacrylate (PMMA).

Indications for Use:
The TRIVANCE™ stems are intended for total and hemi-hip arthroplasty in skeletally mature patients for the following indications:

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 TRIVANCE™ stems are intended for cemented and uncemented applications.

Technological Characteristics:
Subject TRIVANCE™ implants have the same technological characteristics as the predicate devices including design (triple-taper design, coating, neck design, and neck angle), material composition, and function. Subject TRIVANCE™ implants have a similar range of sizes as the predicate devices.

Performance Data:
Performance of the subject stems was evaluated in accordance with the “Guidance for Industry and FDA Staff: Non-clinical Information for Femoral Stem Prostheses,” September 17, 2007. Performance was evaluated by the following mechanical testing and engineering analyses:

- Distal stem fatigue testing (ISO 7206-4)
- Stem neck fatigue testing (ISO 7206-6)
- Range of Motion (ROM) (ISO 21535)
- Distal centralizer mechanical testing
- Dual coating characterization rationale
- Femoral head disassembly performance engineering rationale
- Corrosion performance engineering rationale
- Impingement performance engineering rationale

Performance data demonstrates substantial equivalence to the predicate devices.

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