December 6, 2024

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

Re: K241260
Trade/Device Name: ACTIFY™ Unicondylar Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee Joint Femorotibial Metal/Polymer Non-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: November 4, 2024
Received: November 5, 2024

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.12.06 14:05:31 -05'00'

for: Lixin Liu
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241260

Device Name
ACTIFY™ Unicondylar Knee System

Indications for Use *(Describe)*
The ACTIFY™ Unicondylar Knee System is indicated for unicompartmental knee replacement due to the following conditions:
1. Moderately disabling joint disease of the knee resulting from painful osteo- and/or post-traumatic arthritis, or avascular necrosis.
2. Revision of previous unsuccessful unicompartmental knee replacement or other procedure.
3. Alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.
4. Previous tibial condyle or plateau fractures with loss of anatomy or function.
5. Varus or valgus deformities.

These devices are indicated for cemented use only.

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: ACTIFY™ Unicondylar Knee System

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

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

Date Prepared: December 3, 2024

Device Name: ACTIFY™ Unicondylar Knee System

Common Name: Unicompartmental Knee Prosthesis

Classification: Per 21 CFR as follows:
§888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Product Codes: HSX
Regulatory Class: II, Panel Code: 87

Primary Predicate: StelKast Unicondylar Knee System (K032824)

Additional Predicates: Smith & Nephew ZUK Unicompartmental Knee System (K033363, K230653)
Stryker Triathlon PKR System (K071881, K203099)

Reference Device: GENflex$_2$® Total Knee System (K122883, K162222)

Purpose:
The purpose of this submission is to request clearance for the ACTIFY™ Unicondylar Knee System.

Device Description:
The ACTIFY™ Unicondylar Knee System implants consist of femoral and tibial implants that are used as part of a unicompartmental knee system for partial knee arthroplasty. Implants are available in various configurations and sizes to fit a wide variety of patient anatomy. ACTIFY Unicondylar femoral implants are manufactured from cobalt chrome alloy, tibial inserts are manufactured from ultra high molecular weight polyethylene (UHMWPE) with and without Vitamin E, and tibia trays are manufactured from titanium alloy.

Indications for Use:
The ACTIFY™ Unicondylar Knee System is indicated for unicompartmental knee replacement due to the following conditions:

1. Moderately disabling joint disease of the knee resulting from painful osteo- and/or post-traumatic arthritis, or avascular necrosis.
2. Revision of previous unsuccessful unicompartmental knee replacement or other procedure.
3. Alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.
4. Previous tibial condyle or plateau fractures with loss of anatomy or function.
5. Varus or valgus deformities.

These devices are indicated for cemented use only.

Performance Data:
Performance testing, including fatigue, wear, interlocking strength, constraint and range of motion, and contact area and contact stress, was conducted in accordance with ASTM F1223, ASTM F1814, ASTM F1877, ASTM F2083, ASTM F3140, ASTM F3210, ISO 14243-2, and ISO 14243-3. Performance data demonstrate substantial equivalence to the predicate devices.

Technological Characteristics:
Subject ACTIFY™ Unicondylar Knee System 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:
The subject ACTIFY™ Unicondylar Knee 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.