June 20, 2024

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

Re: K240669
Trade/Device Name: ACTIFY™ 3D Total Knee System
ACTIFY™ Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH, OIY
Dated: May 20, 2024
Received: May 21, 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.

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,

Lixin Liu -S

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

510(k) Number *(if known)*
K240669

Device Name
ACTIFY™ 3D Total Knee System
ACTIFY™ Total Knee System

Indications for Use *(Describe)*
ACTIFY™ Total Knee System and ACTIFY™ 3D Total Knee System are indicated for single use only in skeletally mature individuals undergoing reconstruction of severely disabled and/or very painful joints.

ACTIFY™ Total Knee System and ACTIFY™ 3D Total Knee System are indicated for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post-traumatic degenerative problems, and revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

ACTIFY™ Total Knee System is indicated for cemented use only, except for the porous femoral component which is indicated for both cemented and uncemented use.

ACTIFY™ 3D Total Knee System is indicated for cemented and uncemented use.

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: ACTIFY™ 3D Total Knee System
ACTIFY™ Total 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: June 20, 2024

Device Name: ACTIFY™ 3D Total Knee System
ACTIFY™ Total Knee System

Common Name: Total Knee Joint Replacement

Classification: Per 21 CFR as follows:
§888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
§888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Product Codes: JWH, MBH, OIY
Regulatory Class: II, Panel Code: 87

Primary Predicate: Stryker Triathlon Total Knee System (K173849)

Secondary Predicates: GENflex2® Total Knee System (K162222)
GENflex2® Total Knee System - Ultra-Congruent CR Tibial Insert (K173875)
Proven Cemented Semi-Constrained Total Knee System (K122883, K980276)

Reference Devices: HEDRON® Cervical & Lumbar Spacers, SABLE® Expandable Spacer (K222270)
EXp Acetabular Shell Liner (K094035)

Purpose:
The purpose of this submission is to request clearance for new ACTIFY™ 3D Total Knee System femur, tibia, and patella total knee implants, and expanded indications for cleared GENflex2® implants. GENflex2® implants will be marketed under the ACTIFY™ trade name as the ACTIFY™ Total Knee System.

Device Description:
The ACTIFY™ 3D Total Knee System and ACTIFY™ Total Knee System implants consist of modular femoral, tibial, and patellar implants that are used as part of a complete knee system in total knee arthroplasty. Implants are available in various configurations and sizes to fit a wide variety of patient anatomy. Femoral components and tibial inserts are available in posterior-stabilized (PS) and cruciate-retaining (CR) designs.

Femurs are manufactured from cobalt chromium alloy (CoCr) with a CoCr coating. Tibial inserts and patella implants are manufactured from ultrahigh molecular weight polyethylene (UHMWPE) with and without Vitamin E. ACTIFY™ 3D Total Knee tibia trays and the patella metal base are additively manufactured from titanium alloy powder per ASTM F3001. ACTIFY™ Total Knee tibia trays are manufactured from titanium alloy per ASTM F136.

Indications for Use:
ACTIFY™ Total Knee System and ACTIFY™ 3D Total Knee System are indicated for single use only in skeletally mature individuals undergoing reconstruction of severely disabled and/or very painful joints.

ACTIFY™ Total Knee System and ACTIFY™ 3D Total Knee System are indicated for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post-traumatic degenerative problems, and revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

ACTIFY™ Total Knee System is indicated for cemented use only, except for the porous femoral component which is indicated for both cemented and uncemented use.

ACTIFY™ 3D Total Knee System is indicated for cemented and uncemented use.

Substantial Equivalence Discussion:
ACTIFY™ 3D Total Knee System and ACTIFY™ Total Knee System implants have similar technological characteristics as the predicate devices including design (articular geometry, locking mechanism, material thickness), intended use, material composition, function, and range of sizes. The subject ACTIFY™ 3D and ACTIFY™ femurs differ in porous coating properties, and the ACTIFY™ 3D tibial inserts and trays have an additional mating feature compared to the predicates. These differences are minor and do not raise any new concerns of safety or effectiveness for the subject ACTIFY™ 3D Total Knee System and ACTIFY™ Total Knee System for the intended indications for use.

Performance Data:
Mechanical testing (tray fatigue, A-P shear, shear, and tensile) was conducted in accordance with the “Knee Joint Patellofemorotibial and Femorotibial

Metal/Polymer Porous-Coated Uncemented Prostheses - Class II Special Controls Guidance Document for Industry and FDA Staff," January 16, 2003, ASTM F2083, ASTM F1800, ASTM F1044, ASTM F1147, and ASTM F1672. Performance data demonstrate substantial equivalence to the predicate devices. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

Conclusion:

ACTIFY™ 3D Total Knee System and ACTIFY™ Total Knee System implants have 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.