July 31, 2026

Globus Medical, Inc.
Katherine Warren
Regulatory Specialist
Valley Forge Business Center
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K262251
Trade/Device Name: ACTIFY™ Total Knee System, ACTIFY™ 3D Total Knee System (ACTIFY MC Tibial Insert)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Codes: JWH, MBH, OIY
Dated: July 1, 2026
Received: July 1, 2026

Dear Katherine Warren:

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,

LIXIN LIU -S

Lixin Liu, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262251

Please provide the device trade name(s).

ACTIFY™ Total Knee System, ACTIFY™ 3D Total Knee System (ACTIFY MC Tibial Insert)

Please provide your Indications for Use below.

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 posttraumatic 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.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary: ACTIFY™ Total Knee System, ACTIFY™ 3D Total Knee System (ACTIFY MC Tibial Insert)

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

Primary Contact: Katherine Warren
Regulatory Specialist

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

Date Prepared: July 1, 2026

Device Name: ACTIFY™ Total Knee System,
ACTIFY™ 3D Total Knee System
(ACTIFY MC Tibial Insert)

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 Code(s): JWH, MBH, OIY
Regulatory Class: II

Primary Predicate: ACTIFY™ 3D Total Knee System, ACTIFY Total Knee System (K240669)

Additional Predicates: Proven Knee CR-HF Tibial Insert (K063211, K122883)
ACTIFY™ Total Knee System (K162222, K173875)
J&J MedTech ATTUNE Medial Stabilized Fixed Bearing Insert (K211609)

Purpose:
The purpose of this submission is to request clearance of ACTIFY ™ MC (Medial Conforming) tibial inserts for use with previously cleared ACTIFY ™ 3D and ACTIFY™ (previously GENflex2®) Total Knee System implants.

Device Description:
ACTIFY ™ MC Tibial Inserts are medial conforming tibial insert implants that are used as part of a complete knee system in total knee arthroplasty. Implants are

available in medial conforming designs in various sizes as an additional tibial insert option to fit a variety of patient anatomy. ACTIFY™ MC Tibial Inserts are used with ACTIFY™ 3D Total Knee System and ACTIFY™ Total Knee System implants which consist of modular femoral, tibial, and patellar implants. Tibial inserts are manufactured from ultra high molecular weight polyethylene (UHMWPE) with and without Vitamin E.

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 posttraumatic 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.

Performance Data:
Performance testing, including constraint (AP Draw, ML Shear, and Rotary Laxity) throughout a range of motion, and contact area and contact pressure, was conducted in accordance with ASTM F1223, ASTM F2083, and ISO 21536. Performance data demonstrates substantial equivalence to the predicate devices.

Substantial Equivalence Discussion:
The subject ACTIFY ™ MC Tibial Inserts have the same or similar technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes. ACTIFY™ MC implants differ only in the articulating geometry compared to the primary predicate device. These differences are minor and raise no different concerns of safety or effectiveness for the subject ACTIFY™ MC devices for the intended indications for use.

Conclusion:
The subject ACTIFY™ MC Tibial Inserts 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 device to the predicate devices.