June 14, 2024

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

Re: K240721
Trade/Device Name: ExcelsiusFlex™
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 15, 2024
Received: March 18, 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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2024.06.14 13:24:52 -04'00'

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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)*
K240721

Device Name
ExcelsiusFlex™

Indications for Use *(Describe)*
ExcelsiusFlex™ when used in conjunction with ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of a tool holder to be used by surgeons for navigating and/or guiding compatible surgical instruments provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or directly acquired anatomical structures. The system is indicated to assist the surgeon in planning the position of the implant components and preparing the bony anatomy during orthopedic procedures.

The Total Knee Arthroplasty (TKA) implant systems compatible with ExcelsiusFlex™ are GENflex2® and ACTIFY™ Total Knee System.

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans, fluoroscopy or directly acquired anatomical structures. The system is indicated for the planning of orthopedic devices and placement of spinal and orthopedic bone screws and interbody fusion devices.

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.

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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: ExcelsiusFlex™

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

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

Secondary Contact: Suganya Gopalakrishnan
Regulatory Specialist

Date Prepared: June 12, 2024

Device Name: ExcelsiusFlex™

Common Name: Computer-assisted surgical device

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO
Regulatory Class: II

Primary Predicate: ExcelsiusGPS® (K171651)

Other Predicates: Mako Total Knee Application (K193515)
VELYS™ Robotic-Assisted Solution (K202769)
ExcelsiusHub™ (K211616)
AQrate™(K182000)

Purpose:
The purpose of this submission is to request clearance for the ExcelsiusFlex™ and navigated instruments for bone preparation for primary total knee arthroplasty, and expanded indications for use for ExcelsiusHub.

Device Description:
The ExcelsiusFlex™ is a robotic positioning system with a computer controlled robotic arm, hardware and software that works in conjunction with ExcelsiusHub™, to enable real time surgical navigation and robotic guidance using patient tracking arrays and a positioning camera. The system assists the surgeon in implant placement planning and intraoperative tracking of patient anatomy by locating anatomical structures and stereotaxic positioning of surgical instruments relative to patient CT images or directly acquired anatomical structures. The navigation and guidance system determines the registration or mapping between the virtual patient (points on the patient images) and the physical patient (corresponding

points on the patient's anatomy), or directly acquired anatomical structures. Once this registration is created, the software positions the robotic arm on a planned resection plane.

The ExcelsiusFlex™ is intended for stereotaxic surgery in surgical knee procedures to assist the surgeon in spatial positioning and orientation of a sagittal sawblade, planning the position of the femoral and tibial implants, and for bone preparation during total knee arthroplasty (TKA) procedures. The system constrains the position of the robotic arm to planned resection planes based on the pre-operative or intra-operative plans developed using ExcelsiusFlex™-TKA software on either the ExcelsiusHub™ or a planning laptop.

ExcelsiusFlex™ instruments consist of patient tracking instruments, patient attachment instruments, navigation instruments, end effectors and end effector instruments. Patient attachment instruments provides a point of rigid fixation for the patient tracking instruments. Patient tracking instruments and navigated instruments incorporate unique array patterns with reflective markers, and are used to track patient anatomy and surgical instruments. End effectors attach to the distal end of the robotic arm and provide a rigid connection to the saw blade.

Indications for Use:
ExcelsiusFlex™ when used in conjunction with ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of a tool holder to be used by surgeons for navigating and/or guiding compatible surgical instruments provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or directly acquired anatomical structures. The system is indicated to assist the surgeon in planning the position of the implant components and preparing the bony anatomy during orthopedic procedures.

The Total Knee Arthroplasty (TKA) implant systems compatible with ExcelsiusFlex™ are GENflex2® and ACTIFY™ Total Knee System.

The ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans, fluoroscopy or directly acquired anatomical structures. The system is indicated for the planning of orthopedic devices and placement of spinal and orthopedic bone screws and interbody fusion devices.

Technological Characteristics:
The ExcelsiusFlex™ has similar technological characteristics to the predicate devices including the main system components, workflow, user interface, software features, and design. ExcelsiusFlex™ is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation.

Comparison of Principles of Operation and Technological Characteristics

Device	Subject ExcelsiusFlex™	Predicate Mako Total Knee Application (K193515)	Predicate VELYS Robotic-Assisted Solution (K202769)
Principle of operation	- Preoperative images - Imageless registration or pre-op CT-based patient registration - Surgical planning - Real-time tracking of navigated instruments - Active robot tracking	- Preoperative images - Pre-op CT-based patient registration - Surgical planning - Real-time tracking of navigated instruments - Active robot tracking	- Imageless patient registration - Surgical planning - Real-time tracking of navigated instruments - Active robot tracking
System Components	Base station, robotic arm, camera, display monitor, foot pedal, cutting system, preoperative planning laptop	Guidance Module, robotic arm, camera stand, cutting system, preoperative planning laptop	Base station: camera, power supply, Robot Control Unit, display monitor, foot pedal
Input images	3D pre-operative exam None (Imageless registration)	3D preoperative exam	None (Imageless registration)
Integrated planning software	Yes, Excelsius™-TKA software	Yes	Yes

Performance Testing:
Verification and validation testing were conducted on ExcelsiusFlex™ alone and combined with ExcelsiusHub™ to confirm that the devices meet performance requirements under the indications for use and to ensure safety and efficacy of the system:

- Non-clinical system, software, and instrument verification and validation - demonstrated compliance with user needs and corresponding design inputs
- Surgical simulations conducted on bone models
- Cadaveric quantitative validation under clinically relevant scenarios
- Qualitative validation to confirm intended use
- Electrical Safety and Electromagnetic Compatibility
    - Testing was performed to assure compliance with recognized safety standards for electrical safety and electromagnetic compatibility
        - IEC 60601-1:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: *Electromagnetic disturbances*
- IEC 60601-1-6:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: *Usability*
- IEC 62304:2015 Medical device software - Software lifecycle processes
- IEC 62366:2020 Medical devices - Part 1: Application of usability engineering to medical devices

Software Verification and Validation Testing:
Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (June 14, 2023) and IEC 62304:2006-05 Medical Device Software – Software life cycle processes. The Documentation Level for the software in this device is determined to be “Enhanced Documentation Level”.

Basis of Substantial Equivalence:
ExcelsiusFlex™ 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 to the predicate devices.