July 8, 2025

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

Re: K241525
Trade/Device Name: ExcelsiusXR™
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument.
Regulatory Class: Class II
Product Code: SBF,
Dated: March 21, 2025
Received: March 24, 2025

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,

Shumaya Ali -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241525

Device Name
ExcelsiusXR™

Indications for Use *(Describe)*
ExcelsiusXR™, when used in conjunction with ExcelsiusHub™ and/or ExcelsiusGPS®, is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. This system is indicated for the placement of spinal and orthopedic (Sacroiliac, Ulna, and Tibia) bone screws, and interbody fusion devices.

The ExcelsiusXR™ Headset displays 2D stereotactic images and 3D virtual anatomy images, and displays the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning. This headset should not be relied upon solely for absolute positional information and should always be used in conjunction with the primary stereotactic display.

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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PRAStaff@fda.hhs.gov

"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: ExcelsiusXR™

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

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

Date Prepared: July 7, 2025

Device Name: ExcelsiusXR™

Common Name: Computer-assisted surgical device

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code: SBF (Primary),
Regulatory Class: II

Primary Predicate: Augmedics xvision Spine System (K220905)

Additional Predicates: ExcelsiusHub™ (K211616)
ExcelsiusGPS® (K171651, K191100)

Purpose:
The purpose of this submission is to request clearance for ExcelsiusXR™ and additional instruments.

Device Description:
ExcelsiusXR™ is a head-mounted navigation device, or headset, that is used in conjunction with ExcelsiusHub, and ExcelsiusGPS if robotic guidance is desired, as an aid for precisely locating anatomical structures in open or percutaneous procedures, and for precisely positioning compatible surgical instruments or implants (screws and interbody devices) during surgery. ExcelsiusXR™ includes hardware and software that enables real-time surgical visualization using radiological patient images (preoperative CT, intraoperative CT, and fluoroscopy), provides tracking and planning capabilities for a series of compatible instruments, and contains hand tracking cameras for manipulation of the head-mounted display by the user. The Headset displays 2D stereotactic images and provides a 3D visual, or virtual image, of the patient anatomy in the lower region. The 2D data and 3D model, along with tracking information, are projected to the surgeon's

retina from the transparent near-eye-display Headset, allowing the surgeon to look at the patient and the navigation data at the same time.

Indications for Use:
ExcelsiusXR™, when used in conjunction with ExcelsiusHub™ and/or ExcelsiusGPS®, is intended for use as an aid for precisely locating anatomical structures to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. This system is indicated for the placement of spinal and orthopedic (Sacroiliac, Ulna, and Tibia) bone screws, and interbody fusion devices.

The ExcelsiusXR™ Headset displays 2D stereotactic images and 3D virtual anatomy images, and displays the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning. This headset should not be relied upon solely for absolute positional information and should always be used in conjunction with the primary stereotactic display.

Technological Characteristics:
ExcelsiusXR™ has similar technological characteristics to the predicate devices including function, workflow, user interface, software features, and design. ExcelsiusXR™ 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 ExcelsiusXR™	Predicate Augmedics xvision (K220905)	Predicates ExcelsiusHub (K211616) & ExcelsiusGPS (K171651, K191100)
Intended Use Environment	Operating Room	Operating room	Operating room
Principle of Operation	• Intraoperative/ Preoperative images • Patient registration • Surgical planning (optional) • Real-time tracking of navigated instruments • Manual, free hand or robotic guidance of instruments • Hand tracking	• Patient Preparation • System Set-Up • Interoperative Scan • Scan Import • Patient Registration • Navigation	• Intraoperative/ Preoperative images • Patient registration • Surgical planning (optional) • Real-time tracking of navigated instruments • Manual, free hand or robotic guidance of instruments
Integrated Planning Software	Excelsius Planning and Navigation Application software	XVS Software	Excelsius Planning and Navigation Application software
Save/load Planning	Yes	No	Yes
Merge Images Functionality	Yes	No	Yes

Device	Subject ExcelsiusXR™	Predicate Augmedics xvision (K220905)	Predicates ExcelsiusHub (K211616) & ExcelsiusGPS (K171651, K191100)
Image-guided	Yes	Yes	Yes
Patient Registration Method	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture Excelsius3D™ CT Excelsius3D™ fluoroscopy	Intra-Op CT: Registration Fixture	Intra-Op CT: Registration Fixture Pre-Op CT: Fluoroscopic to Pre-Op CT Merge Fluoroscopy: Registration Fixture Excelsius3D™ CT Excelsius3D™ fluoroscopy
Accuracy Verification on Anatomical Landmarks	Yes	N/A	Yes
Real Time Display of the Instrument Position	Yes	Yes	Yes
Patient Fixation	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system.	Reference is fixed to patient's spinous process for tracking system.	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system.

Performance Testing:

Verification and validation testing were conducted on ExcelsiusXR™ to confirm that the device meets 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 phantom models
- Qualitative and quantitative validation to confirm intended use and accuracy
- Optical bench testing to evaluate the image quality characteristics of the head mounted display
- 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 60601-1-2:2020 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 62366-1:2020 Medical devices - Part 1: Application of usability engineering to medical devices

Software Verification and Validation Testing:
Software verification and validation testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Device Software Functions, June 14, 2023. The software for this device was determined to require "Enhanced Documentation".

Basis of Substantial Equivalence:
ExcelsiusXR™ 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.