April 29, 2024

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

Re: K240568
Trade/Device Name: DuraPro™ Oscillating System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 29, 2024
Received: February 29, 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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240568

Device Name

DuraPro™ Oscillating System

Indications for Use *(Describe)*

The DuraPro™ Oscillating System is indicated for drilling, burring, removing, and otherwise manipulating hard and soft tissue, bone, and other bone related tissue during spinal and orthopedic procedures.

ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube 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. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

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 or fluoroscopy. The system is indicated for the 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: DuraPro™ Oscillating System

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

Date Prepared: February 29, 2024

Device Name: DuraPro™ Oscillating System

Common Name: Orthopedic Stereotaxic Instrument

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO
Regulatory Class: II, Panel Code: 87

Primary Predicate: VERZA™ High Speed Drills (K233638)

Additional Predicates: Medtronic Stealth-Midas MR8 System (K183644)
ExcelsiusGPS® High Speed Drill Instruments (K190653)
ExcelsiusGPS® (K171651, K191100)
ExcelsiusHub™ (K211616)

Reference Devices: Electrical Drill System [XPS4000, Midas Rex EHS system, Integrated Power Console (IPC)] (K081475)
HEDRON® Cervical & Lumbar Spacers, SABLE® Expandable Spacer (K222270)

Purpose:
The purpose of this submission is to request clearance of DuraPro™ Oscillating System for use with ExcelsiusGPS® and ExcelsiusHub™.

Device Description:
The DuraPro™ Oscillating System consists of electrical drill handpieces/attachments powered by an oscillating motor with a foot switch, and may be navigated using ExcelsiusGPS® or ExcelsiusHub™. The navigated components are provided non-sterile and are reusable. Attachments are provided sterile and are single-use.

Indications for Use:
The DuraPro™ Oscillating System is indicated for drilling, burring, removing, and otherwise manipulating hard and soft tissue, bone, and other bone related tissue during spinal and orthopedic procedures.

ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube 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. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

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 or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.

Technological Characteristics:
The subject DuraPro™ Oscillating System has the same technological characteristics as predicate instruments including design, intended use, material composition, function, and range of sizes.

Features	**Subject DuraPro™ Oscillating System**	**Predicate & Reference Devices**
Indications	The DuraPro™ Oscillating System is indicated for drilling, burring, removing, and otherwise manipulating hard and soft tissue, bone, and other bone related tissue during spinal and orthopedic procedures. ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube 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. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices. ExcelsiusHub™ is intended for use as an aid for precisely locating anatomical structures to be used	Similar

Features	Subject DuraPro™ Oscillating System	Predicate & Reference Devices
	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 or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws and interbody fusion devices.	
Instruments	Navigated and guided instruments	Same
Materials	Stainless steel, PEEK, Radel, Titanium alloy	Same
Biocompatibility	Stainless steel, PEEK, Radel, and titanium alloy have a history of biocompatibility as instrument materials per ASTM specifications and predicate devices.	Same
Performance	The navigation and guidance accuracy of the DuraPro™ Oscillating System was evaluated using intra-operative imaging and accuracy verification testing. Testing confirmed that accuracy values meet the product requirement specification.	
Electrical Safety/EMC	Electrical safety and EMC testing were conducted on the DuraPro™ Oscillating System. Testing confirmed the system meets all standards.	

Performance Testing:
The navigation and guidance accuracy of the DuraPro™ Oscillating System was evaluated using intra-operative imaging and accuracy verification testing. Testing confirmed that accuracy values meet the product requirement specification. Verification and validation testing and comparison to the predicate devices demonstrate that the subject DuraPro™ Oscillating System can be used in accordance with their indications.

Basis of Substantial Equivalence:
The DuraPro™ Oscillating 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 device to the predicate devices.