



April 23, 2025

LEM Surgical AG
% Alexia Haralambous
Senior Principal
RQM+
2790 Mosside Blvd, #800
Monroeville, Pennsylvania 15146

Re: K243326

Trade/Device Name: Dynamis Robotic Surgical System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 23, 2025
Received: April 23, 2025

Dear Alexia Haralambous:

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,

Tejen D. Soni -S

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

Indications for Use

Submission Number (if known)

K243326

Device Name

Dynamis Robotic Surgical System

Indications for Use (Describe)

The Dynamis Robotic Surgical System 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 qualified surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on intraoperative CT scans. The Dynamis Robotic Surgical System is indicated for the placement of non-cervical spinal pedicle screws.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@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."

K243326 510(k) SUMMARY**DATE PREPARED**

April 23, 2024

MANUFACTURER AND 510(k) OWNER

LEM Surgical AG
Morgenstrasse 136
3018 Bern, Switzerland
Telephone: +41 31 382 30 00
Official Contact: Yossi Bar, Chief Executive Officer

REPRESENTATIVE/CONSULTANT

Alexia Haralambous, Senior Principal
RQM+
Telephone: +1 (267) 778-5114
Email: aharalambous@rqmplus.com

DEVICE INFORMATION

Proprietary Name/Trade Name: Dynamis Robotic Surgical System
Common Name: Orthopedic Stereotaxic Instrument
Regulation Number: 21 CFR 882.4560
Class: II
Product Code: OLO
Premarket Review: CDRH/OPEQ/OHT6/DHT6C
Review Panel: Orthopedic

PREDICATE DEVICE IDENTIFICATION

The Dynamis Robotic Surgical System is substantially equivalent to the following predicate device:

<i>510(k) Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>
K171651	EXCELSIUS GPS / Globus Medical, Inc.	✓

DEVICE DESCRIPTION

The Dynamis System is an integrated navigation-based robotic platform with real-time tracking capability for spine surgical procedures that include thoracic, lumbar, and sacral approaches. Dynamis 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 qualified surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans. The system is indicated for the placement of non-cervical spinal pedicle screws and is intended for use with any legally marketed spinal system that contains instruments meeting the criteria for use with the Dynacan end effectors of the Dynamis System.

The Dynamis System is comprised of two computer-controlled robotic arms to support surgical robotic guidance, while a third robotic arm holds and controls the Scout navigation camera. All

components are integrated into one physical cart located partially underneath the surgical table.

The Dynamis Robotic Surgical System functions as a stable platform that operates with intraoperative DICOM format images for intraoperative planning and operation. The system software is responsible for all motion, control, navigation, data storage, user management, case management, and safety functions. The navigation and guidance system establishes registration between the virtual patient (points on the patient images) and the physical patient (corresponding to the patient's bony anatomy). The information of the plan, coupled with the registration, provides the necessary information to give visual assistance to the surgeon during freehand navigation or during the robotic alignment of instruments. Navigation can also be achieved without robotic guidance with the proprietary navigation instruments provided with the Dynamis system.

Dynamis is designed and intended to be used with qualified surgical instruments, which are defined as legally marketed instruments that meet pre-specified criteria and that pass the Instrument Setup process, which is an instrument verification test integrated into the Dynamis Robotic Surgical System. To qualify a surgical instrument for use through the Dynacan, it must be legally marketed and meet the following criteria:

- Round
- Straight
- Rigid
- Concentric

In addition, the user must accurately measure the effective length of the instruments using the Dynamis system during the set-up phase.

The navigation-based robotic capabilities of Dynamis are intended for use with a variety of legally marketed, qualified surgical implantation instruments, as the adjustable end effector (Dynacan) is able to mechanically support a wide range of device diameters from 3 mm to 20 mm in diameter, including legally marketed taps and screwdrivers which can be checked and qualified by the user implementing the Dynamis Instrument Setup.

INDICATIONS FOR USE

The Dynamis Robotic Surgical System 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 qualified surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on intraoperative CT scans. The Dynamis Robotic Surgical System is indicated for the placement of non-cervical spinal pedicle screws.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

LEM Surgical believes that the subject Dynamis system is similar in technological characteristics to the predicate EXCELSIUS GPS system. Both systems consist of at least one robotic arm, an optical camera, surgical instruments, system software, and a cart. Both systems achieve patient registration using a combination of radiopaque and optic markers on the patient fixation fixtures and instrument guidance using optic markers on the end effectors on the robotic arm. However,

the EXCELSIUS GPS system additionally uses a separate set of optic markers on several instruments related to its proprietary implant set, while Dynamis is not specific for use with a proprietary implant set and relies on end effector guidance of the surgical instruments. The EXCELSIUS GPS end effector is comprised of a fixed diameter guide tube which is attached to the robotic arm, while the Dynamis system utilizes an adjustable end effector ('Dynacan') that enables the facilitation of various instrument diameters. The Dynamis system is intended for use with 'qualified instruments,' i.e., non-proprietary instruments that pass the Instrument Setup, whereas the EXCELSIUS system is only compatible with proprietary pre-calibrated instrument systems. Finally, the Dynamis system integrates all components into a single cart system, whereas EXCELSIUS comprises of two carts to house the system components. The table below provides additional detail on the comparison of the Dynamis system with the predicate device.

	Subject Device: Dynamis Robotic Surgical System	Primary Predicate: EXCELSIUS GPS
Manufacturer	LEM Surgical AG	Globus Medical, Inc.
Submission Number	K243326	K171651
Regulation Number	21 CFR 882.4560	21 CFR 882.4560
Regulation Name	Stereotaxic Instrument	Stereotaxic Instrument
Regulatory Class	Class II	Class II
Product Code	OLO	OLO
Indications for Use	The Dynamis Robotic Surgical System 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 qualified surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on intraoperative CT scans. The Dynamis Robotic Surgical System is indicated for the placement of non-cervical spinal pedicle screws.	The Excelsius GPS™ 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.
Imaging Modality	3D intraoperative imaging	3D preoperative imaging 2D intraoperative imaging 3D intraoperative imaging
Integrated Planning & System Software	Dynamis Robotic Surgical Software	EXCELSIUS™ GPS Planning and Navigation Software
DICOM Compatibility & Storage	Yes	Yes
Navigation system	Optical camera	Optical camera
Controller	Force-controlled movement via Foot Pedal and Squeeze Bracelet ('Dynacuff')	Force-controlled movement via Foot Pedal or Squeeze Bracelet
Surgical Workflow	Freehand and Robotic-Guided	Freehand and Robotic-Guided
Patient Fixation	Reference is fixed to bony structure for tracking system	Reference is fixed to bony structure for tracking system
Patient Registration	Patient marker on registration fixture	Patient marker on registration fixture
Instrument Tracking/Verification	Dynacan end effector with markers + Instrument Setup step	Robotic arm end effector with markers + registration markers for each instrument + individual instrument verification

	Subject Device: Dynamis Robotic Surgical System	Primary Predicate: EXCELSIUS GPS
Implant/Instrument System Compatibility	End effector tracking with qualified instruments	End effector tracking + specific implant/instrument systems
System configuration	2 Robotic Arms, 1 Arm containing optical camera, control screen, instruments, system software, all integrated into a single cart located partially underneath surgical table	1 Robotic Arm & 1 monitor located on the Robotic Base Station, optical camera located on the Camera Stand, instruments, system software
Safety Features	Emergency stop button & system Surface mapping Collaborative Robot	Emergency stop button

SUMMARY OF NON-CLINICAL TESTING

Verification and validation testing was conducted on the subject Dynamis system to demonstrate substantial equivalence and in accordance with standards, where applicable. The following tests were conducted:

- Non-clinical system and instrument verification and validation testing
- Navigation accuracy verification per ASTM F2554-22
- Quantitative system level accuracy validation in a clinically relevant model
- Software verification and validation per IEC 62304 & IEEE/ISO/IEC 29119-1-2-3-5-2021
- Cybersecurity testing per IEC 62304:2006/AMD 1:2015, IEC 81001-5-1:2021, AAMI TIR57:2016/(R)2023
- Electromagnetic and Electrical Safety testing per IEC 60601-1:2005, IEC 60601-1-2:2014, IEC 80601-2-77:2019, IEC 60601-1-6:2010, IEC 60601-1-8: IEC 60601-1-8:2006, and IEC 60825-1:2014
- Biocompatibility testing per ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-23:2021, ISO 10993-10:2021, ISO 10993-11:2017
- Cleaning and sterilization validation per ANSI/AAMI ISO 17665-1: 2006/(R) 2013, AAMI ST98:2022, AAMI TIR12:2020, AAMI TIR30:2011/(R)2016, EN ISO 17664-1:2021
- Human factors/usability testing per ANSI AAMI IEC 62366-1:2015 & AAMI/ANSI HE75:2009/(R)2018

CONCLUSION

The data demonstrate substantial equivalence of the subject Dynamis Robotic Surgical System to the predicate Globus EXCELSIUS GPS System. Based on the testing performed, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices. Therefore, the subject Dynamis system is substantially equivalent to the predicate device with respect to intended use, principle of operation, technological characteristics, and performance.