June 20, 2026

LEM Surgical AG
% Alexia Haralambous
Principal Consultant
Harmonia Insights, LLC
6800 Wisconsin Ave.
#1280
Chevy Chase, Maryland 20815

Re: K260369
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: June 16, 2026
Received: June 16, 2026

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 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,

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

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.	K260369

Please provide the device trade name(s).

Dynamis Robotic Surgical System

Please provide your Indications for Use below.

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 spinal pedicle screws.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) SUMMARY - K260369

DATE PREPARED
February 4, 2026

MANUFACTURER AND 510(K) OWNER
LEM Surgical AG
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REPRESENTATIVE/CONSULTANT
Alexia Haralambous, MS, RAC
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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:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K243326	Dynamis Robotic Surgical System / LEM Surgical AG	✓

DEVICE DESCRIPTION
The Dynamis System is an integrated navigation-based robotic platform with real-time tracking capability for spine surgical procedures that include cervical, thoracic, lumbar, and sacral approaches. The system was previously cleared under K243326. The purpose of this submission is to introduce modifications to the previously cleared Dynamis System to expand navigation capabilities, enhance vertebra tracking, and add workflow improvements, while maintaining the same intended use and fundamental scientific technology.

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 cart employs bilateral elevator mechanisms to deploy and fold the surgical robotic arms and secure them. This system functions in conjunction with different intraoperative imaging systems by data transfer of DICOM format images by USB and/or Direct LAN transfer for intraoperative

planning. The system software is responsible for all motion control, navigation, data storage, user management, case management, and safety functions.

The system establishes registration between the virtual patient (points on the patient DICOM images) and the physical patient (corresponding to the patient's anatomy). The information of the plan, coupled with the registration, provides the necessary information to give visual assistance to the surgeon during the robotic alignment of qualified instruments or during freehand navigation. Qualified instruments that are rigid, straight, round, and concentric are permitted for use through the Dynacan or used with the Dynatracker (i.e., navigation tracker attached to hand-held instrument), given they pass the Instrument Setup process.

The system also supports individual vertebra tracking to maintain alignment to vertebra specific trajectories by monitoring relative vertebral motion, as well as a stabilization workflow which provides additional control of vertebral motion during instrumentation.

The instruments included in the system include a registration marker, patient reference markers (Patient Marker and Vertebra Markers), surgical instruments, Dynacans (end effectors), and Dynatrackers (Universal Markers). The instruments are reusable and supplied non-sterile to the user. The user is responsible for cleaning and sterilization of the instruments per the provided instructions.

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 spinal pedicle screws.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject Dynamis System includes modifications to the previously cleared Dynamis System, including expanded freehand navigation support, individual vertebra tracking using additional bone-mounted markers, stabilization workflow options, introduction of cervical indications, and user interface refinements to support these capabilities.

These modifications do not introduce new fundamental scientific technology. The subject device continues to rely on the same core architecture and principles as the predicate Dynamis System, including a multi-arm robotic platform integrated into a single cart, an optical tracking camera, bone-mounted reference markers, end effector-based instrument tracking, software-based planning, registration, navigation, and robotic alignment, force-controlled arm movement via the Dynacuff and foot pedal, and the same underlying optical tracking, robotic guidance, and DICOM-based planning framework. The proposed updates extend and refine the predicate system's established technological characteristics without altering its fundamental scientific basis.

The modifications do not raise new or different questions of safety or effectiveness. The subject

device continues to operate within the same safety framework and uses the same tracking principles, robotic arm architecture, force-controlled movement, and navigation algorithms as the predicate device, leveraging previously cleared mechanisms for tracking, instrument control, and force detection.

	Subject Device: Dynamis Robotic Surgical System	**Primary Predicate: Dynamis Robotic Surgical System**
Manufacturer	LEM Surgical AG	LEM Surgical AG
Submission Number	K260369	K243326
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 spinal pedicle screws.	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.
Imaging Modality	3D intraoperative imaging	3D intraoperative imaging
Integrated Planning & System Software	Dynamis Robotic Surgical Software	Dynamis Robotic Surgical 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 and Squeeze Bracelet (‘Dynacuff’)
Surgical Workflow	Freehand and Robotic-Guided; includes optional stabilization mode.	Freehand and Robotic-Guided
Patient Fixation & Reference Marker Options	Bone-mounted Patient Marker; Bone-mounted Vertebra Marker.	Bone-mounted Patient Marker.

	Subject Device: Dynamis Robotic Surgical System	**Primary Predicate: Dynamis Robotic Surgical System**
Registration & Tracking Architecture	Patient marker on registration fixture; system can track patient reference frame and update trajectories based on individually assigned vertebrae.	Patient marker on registration fixture
Instrument Tracking/Qualification	Dynacan end effector with markers + Instrument Setup step, including support for freehand navigation instruments via Dynatracker	Dynacan end effector with markers + Instrument Setup step
Implant/Instrument System Compatibility	End effector tracking with qualified instruments	End effector tracking with qualified instruments
Robotic Guidance Trajectory Accuracy	Up to 1.5mm and 2 degrees	Up to 1.5mm and 2 degrees
System Navigation Accuracy	Robotic-Guided: Up to 1.5mm and 2 degrees Freehand: Up to 2mm and 2 degrees	Robotic-Guided: Up to 1.5mm and 2 degrees
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	2 Robotic Arms, 1 Arm containing optical camera, control screen, instruments, system software, all integrated into a single cart located partially underneath surgical table
Safety Features	Emergency stop button & system Surface mapping Collaborative Robot	Emergency stop button & system Surface mapping Collaborative Robot

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 (cadaver)
- 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 Dynamis Robotic Surgical System. The subject Dynamis system is substantially equivalent to the predicate device with respect to intended use, principle of operation, technological characteristics, and performance.