January 12, 2026

Promethean Restorative LLC
Glenn Bowman
VP Regulatory
330 Perry Street, Suite 210
Castle Rock, Colorado 80104

Re: K252962
Trade/Device Name: DYNAMIS™ Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 11, 2025
Received: December 11, 2025

Dear Glenn Bowman:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252962

Device Name
DYNAMIS™ Navigation System

Indications for Use *(Describe)*
The DYNAMIS™ Navigation System is intended to be used in the preparation and placement of the DYNAMIS™ Implant System during sacroiliac joint fusion surgery and fracture fixation of the pelvis to assist the surgeon in guiding instrument placement and implant positioning, in which the use of stereotaxic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis, or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image based model of the anatomy. The DYNAMIS™ Navigation System is intended to be used with the Medtronic StealthStation S8 System, Software Version 2.1.

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
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

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

Company: Promethean Restorative Inc.
333 Perry Street, Suite 210
Castle Rock, CO 80104
USA

Contact: Glenn Bowman
(720) 512-5947
regulatory@prometheanrestorative.com

Date Prepared: December 19, 2025

Device Trade Name: DYNAMIS™ Navigation System
Common Name: Stereotaxic instrument
Classification: 21 CFR §882.4560
Class: II
Product Code: OLO

Primary Predicate: Precision Spine Navigation System (K181606)
Additional Predicates: Medtronic Navigated Reusable Instruments for use with StealthStation™ and IPC™ Powerease™ Systems (K210637)
Navigated CD Horizon Solera Screwdriver/Taps (K140454)
Innovasis Navigation Instruments (K250182)
Reference Device: DYNAMIS™ Implant System (K251075)

Device Description:
The DYNAMIS™ Navigation System consists of non-sterile, reusable, manual surgical instruments for use with the Medtronic StealthStation® Navigation System to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures.

The DYNAMIS™ Navigation System includes drivers, taps, and awls which are used with the DYNAMIS™ Implant System. All instruments are made of stainless steel per ASTM F899.

The DYNAMIS™ Navigation System instruments are not compatible with implants from other manufacturers and are designed for use only with Medtronic StealthStation® System S8 and the Medtronic NavLock® Tracker System.

Indications For Use:
The DYNAMIS™ Navigation System is intended to be used in the preparation and placement of the DYNAMIS™ Implant System during sacroiliac joint fusion surgery and fracture fixation of the pelvis to assist the surgeon in guiding instrument placement and implant positioning, in which the use of stereotaxic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis, or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image based model of the anatomy. The DYNAMIS™ Navigation System is intended to be used with the Medtronic StealthStation S8 System, Software Version 2.1.

Substantial Equivalence:
The DYNAMIS™ Navigation System has been demonstrated to be substantially equivalent with respect to indications and performance as compared to the predicate devices.
The DYNAMIS™ Navigation System has the same technological characteristics with respect to design, materials, function, manufacturing, and/or performance as compared to the predicate devices.

Performance Data:
An Engineering analysis and geometric comparison of the predicate devices compared to the DYNAMIS™ Navigation System instruments was performed to establish the safety and efficacy for accuracy performance. In addition, functional verification testing demonstrated that the subject instruments adequately registered with the navigation system and appropriately fit with the previously cleared devices.

Conclusion:
Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject DYNAMIS™ Navigation System has been shown to be substantially equivalent to legally marketed predicate devices.