



April 25, 2025

Promethean Restorative LLC
Glenn Bowman
President and CEO
333 Perry Street, Suite 210
Castle Rock, Colorado 80104

Re: K251075

Trade/Device Name: DYNAMIS™ Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, HWC
Dated: April 4, 2025
Received: April 8, 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,

Maziar Shah Mohammadi

For: Colin O'Neill, M.B.E

Assistant Director

DHT6B: Division of Spinal 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.

K251075

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Please provide the device trade name(s).

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DYNAMIS™ Implant System

Please provide your Indications for Use below.

The DYNAMIS™ Implant System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The DYNAMIS™ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute and nontraumatic fractures.

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

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

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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 LLC
333 Perry Street, Suite 210
Castle Rock, CO 80104

Contact: Glenn Bowman
Promethean Restorative LLC
333 Perry Street, Suite 210
Castle Rock, CO 80104
Phone: 303-330-8773
regulatory@prometheanrestorative.com

Date Prepared: April 21, 2025

Device Trade Name: DYNAMIS™ Implant System
Common Name: Sacroiliac Joint Fixation
Classification: 21 CFR §888.3040
Classification Name: Smooth or threaded metallic bone fixation fastener
Class: II
Product Code: OUR, HWC

Primary Predicate: DYNAMIS™ SI Screw System (K243565)
Reference Device: Nanovis Nano FortiFix (K193211)

Device Description:

The DYNAMIS™ Implant System consists of threaded, fenestrated, cannulated, 3D-printed implants and associated instruments. The implants are constructed from medical grade titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The implants are fully threaded with a lag design and a cannulated central threaded body. To accommodate varying patient anatomy, the DYNAMIS™ Implants are available in multiple diameters and length offerings. The implants allow for packing of autograft and allograft materials. Using the designated instrument system, two or more implants should be inserted across the SI Joint to apply a compressive force across the joint and to provide stabilization and fusion. The DYNAMIS™ implants are single use devices that are provided sterile. The DYNAMIS™ Implant System is comprised of DYNAMIS™ Screws and DYNAMIS™ TRU-NANO Screws.

DYNAMIS™ TRU-NANO Screws: The surfaces of the DYNAMIS™ TRU-NANO Screws incorporate a micro- and nano-roughened surface that demonstrates the requirements for nanotechnology. The surface of the screws have been deliberately manipulated to produce nanoscale dimensions which exhibit specific properties. These screws are electrochemically treated to possess a controlled nanotopography



composed of nanotube arrays having a pore size diameter between 30-97 nanometers. Calcium and phosphate are incorporated into the nanotube surface.

Indications For Use:

The DYNAMIS™ Implant System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The DYNAMIS™ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute and nontraumatic fractures.

Substantial Equivalence:

The DYNAMIS™ Implant System has been demonstrated to be substantially equivalent with respect to indications, design, materials, function, manufacturing, and performance as compared to the predicate devices.

Performance Data:

Testing on the DYNAMIS™ Implant System included static cantilever bending and dynamic cantilever bending per ASTM F3574, as well as static axial pullout, static torsion, and driving torque per ASTM F543. The results demonstrate that the DYNAMIS™ Implant System is substantially equivalent to the predicate devices.

To address the “Points to Consider” in the FDA’s *Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*, in vitro evaluations were relied upon which quantitated the mineralization of extracellular matrix secreted by osteoblasts (OB) and mesenchymal stem cells (MSC) on surfaces created from a titanium alloy substrate. The in vitro study results demonstrated that the DYNAMIS™ TRU-NANO Screw nanosurface develops statistically significantly greater mineralization in both osteoblast and mesenchymal stem cell cultures compared to other surfaces.

Bacterial endotoxin testing was conducted in accordance with AAMI ST72:2011 and met the specified testing limit.

Conclusion:

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