August 5, 2025

Bethesda Medical Devices
Amanda Shade
Director of QA/RA
2985 Nationwide Parkway
Brunswick, Ohio 44212

Re: K252113
Trade/Device Name: PRADO™ Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 3, 2025
Received: July 7, 2025

Dear Amanda Shade:

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,

Katherine D. Kavlock -S

for

Brent Showalter, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252113

Device Name
PRADO™ Lumbar Interbody Fusion System

Indications for Use *(Describe)*
The PRADO™ Lumbar Interbody Fusion System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis and/or stenosis at the involved level(s). Additionally, the Prado™ Lumbar Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. It is indicated to be used with autograft bone and/or allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate or a bone void filler cleared for use in intervertebral body fusion to facilitate fusion.

Additionally, the use of hyperlordotic devices (lordotic angle greater than 20°) are intended to be used exclusively with anterior supplemental fixation.

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.

BETHESDA MEDICAL DEVICES

510(k) Summary

As required by section 807.92(c)

Bethesda Medical Devices, LLC is requesting marketing clearance for the PRADO™ Lumbar Interbody Fusion System

A. Sponsor/Manufacturer:

Bethesda Medical Devices, LLC
Amanda Shade, Director of QA/RA
2985 Nationwide Parkway
Brunswick, OH 44212
330-980-8681
amanda@ptsmfg.com

B. Date: 7/31/2025

C. Trade Name: PRADO™ Lumbar Interbody Fusion System
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080 Class II, Product Code MAX)

D. Primary Predicate Device: K141443 (InFront Lumbar Interbody Fusion System)
Additional Predicate: K241375 (Transcend PEEK Interbody System)
K170395 (Talos Intervertebral Body Fusion Devices)

E. Device Description:

PRADO™ Lumbar Interbody Fusion System consists of a series of implants and device specific instruments. PRADO™ Lumbar Interbody devices are manufactured from polyetheretherketone (PEEK) or Hydroxyapatite (HA) filled Polyetheretherketone (PEEK). The superior and inferior surfaces of the implants have ridges to interface with the vertebral endplates to resist rotation and migration. Additionally, the cephalad / caudal opening of each implant is maximized to facilitate bone through growth. Lateral fenestrations are provided to encourage bone ingrowth. Tantalum markers (per ASTM F560) or titanium (per ASTM F136), are configured as rods at the extremes of the PRADO™ Lumbar Interbody Devices to allow for radiological confirmation of the positioning. The proximal face of each interbody has a threaded thru hole which is to be used to interface with the inserter.

PRADO™ Lumbar Interbody Devices are available in four footprints to coincide with the surgical approach and patient need: PRADO™ P, PRADO™ T, PRADO™ L and PRADO™ A. The implants are available in a range of sizes to accommodate variations in patient anatomy.

F. Intended Use / Indications for Use:

BETHESDA MEDICAL DEVICES

The PRADO™ Lumbar Interbody Fusion System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis and/or stenosis at the involved level(s). Additionally, the Prado™ Lumbar Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis and sagittal deformity. It is indicated to be used with autograft bone and/or allogenic bone graft comprised of cortical, cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate or a bone void filler cleared for use in intervertebral body fusion to facilitate fusion.

Additionally, the use of hyperlordotic devices (lordotic angle greater than 20°) are intended to be used exclusively with anterior supplemental fixation.

G. Technological Characteristics:

The technological characteristics of the PRADO™ Lumbar Interbody Devices are identical to the previously cleared device with the exception of:

- Expanding shape, size and lordotic angles for the interbodies
- The option to provide the product sterile
- The option to utilize tantalum or titanium rods for markers
- The option to use HA PEEK as the material for the interbodies

H. Non-clinical Testing:

Testing according to ASTM F2077-18 and ASTM F2267-04 was performed on the previously cleared InFront Lumbar Interbody Fusion Devices. The tests included static compression, dynamic compression, expulsion and subsidence. Engineering analysis was performed on the subject devices to confirm that a new worst-case is not presented in the proposed devices.

I. Conclusion:

The fundamental scientific technology of the PRADO™ Lumbar Interbody system and the proposed device allows for substantial equivalency between them.