



July 16, 2026

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

Re: K261309

Trade/Device Name: Palisades™ Buttress Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 20, 2026
Received: April 21, 2026

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 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,


**EILEEN
CADEL-S** 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

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.

K261309

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Please provide the device trade name(s).

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Palisades™ Buttress Plate System

Please provide your Indications for Use below.

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The Palisades™ Buttress Plate System is a non-load bearing plate system that may be used in the thoracic, lumbar and sacral spine (T1-S1). The Palisades™ Buttress Plate System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts and autografts. This device is not intended for load bearing applications.

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](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☐ Children (2 years old to < 12 years old)

☐ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) #:

510(k) Summary

Prepared on: 2026-07-16

Contact Details[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Bethesda Medical Devices, LLC
Applicant Address	2985 Nationwide Parkway Brunswick OH 44212 United States
Applicant Contact Telephone	330-980-8681
Applicant Contact	Amanda Shade
Applicant Contact Email	amanda@ptsmfg.com

Device Name[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Palisades™ Buttress Plate System
Common Name	Spinal intervertebral body fixation orthosis
Classification Name	Appliance, Fixation, Spinal Intervertebral Body
Regulation Number	888.3060
Product Code(s)	KWQ

Legally Marketed Predicate Devices[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K143065	NuVasive ALIF Buttress Plate System	KWQ

Device Description Summary[21 CFR 807.92\(a\)\(4\)](#)

The Palisades™ Buttress Plate System consists of plates of various sizes to accommodate varying patient anatomy and surgical needs. The Palisades™ plates are utilized with bone screws to attach to the vertebral body of the thoracolumbar spine. The Palisades™ Buttress Plate is a non-load bearing plate system manufactured from Ti-6Al-4V ELI per ASTM F136 and is utilized to prevent migration or expulsion of allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. Additionally, the plate features spikes to prevent rotation and a window to allow visualization of the interdiscal space. Multiple screw diameters and screw lengths are available to secure the plate to the vertebral body.

Intended Use/Indications for Use[21 CFR 807.92\(a\)\(5\)](#)

The Palisades™ Buttress Plate System is a non-load bearing plate system that may be used in the thoracic, lumbar and sacral spine (T1-S1). The Palisades™ Buttress Plate System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts and autografts. This device is not intended for load bearing applications.

Indications for Use Comparison[21 CFR 807.92\(a\)\(5\)](#)

The Palisades™ Buttress Plate System and the predicate device have the same intended use.

Technological Comparison[21 CFR 807.92\(a\)\(6\)](#)

The Palisades™ Buttress Plate System and the predicate device are single use devices, manufactured from the same material, and packaged as non-sterile requiring steam sterilization prior to use. The Palisades™ Buttress Plate System and the predicate device differ in

size, shape, fixation spike geometry, and locking mechanism design.

Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

The mechanical performance of the Palisades™ Buttress Plate System was evaluated per modified ASTM F2193 and ASTM F543.

Clinical Testing is not applicable for the Palisades™ Buttress Plate System.

Nonclinical testing demonstrated that the Palisades™ Buttress Plate System performs substantially equivalent to the predicate device.