July 31, 2026

Foundation Surgical Group
Christopher Reah
Quality and Regulatory Affairs
7327 E Tierra Buena Lane
Suite 101
Scottsdale, Arizona 85260

Re: K261809
Trade/Device Name: Interwedge® Standalone Lateral
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: July 6, 2026
Received: July 6, 2026

Dear Christopher Reah:

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,

BRENT SHOWALTER -S

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

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.	K261809

Please provide the device trade name(s).

Interwedge® Standalone Lateral

Please provide your Indications for Use below.

The Interwedge® Standalone Lateral is a standalone lateral lumbar interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L1-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The Interwedge® Standalone Lateral is to be filled with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone, and is to be used with the two titanium alloy screws which accompany the implant. Should a physician choose to use fewer than these two screws, additional supplemental fixation must be used to augment stability.

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)

510(k) #: K261809

510(k) Summary

Prepared on: 2026-07-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Foundation Surgical Group
Applicant Address	7327 E Tierra Buena Lane Suite 101 Scottsdale AZ 85260 United States
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Correspondent Address	7327 E Tierra Buena Lane Suite 101 Scottsdale AZ 85260 United States
Correspondent Contact Telephone	+44 7490 710629
Correspondent Contact	Dr. Christopher Reah
Correspondent Contact Email	creah@foundationsurgical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Interwedge® Standalone Lateral
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Integrated Fixation, Lumbar
Regulation Number	888.3080
Product Code(s)	OVD

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241487	Interwedge® Standalone Lateral	MAX

Device Description Summary

21 CFR 807.92(a)(4)

The Interwedge® Standalone Lateral (Interbody & Plate) is a standalone lateral lumbar interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The Interwedge® is available in a variety of heights and geometric options to accommodate variations in pathology and patient anatomy. Protrusions on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to aid in expulsion resistance. The Interwedge® is to be filled with autogenous bone graft and/or allogeneic bone graft material and is to be used with the titanium alloy bone screws to provide fixation. Bone screws are used to attach to the ipsilateral portion of the adjacent vertebral bodies for bony fixation. The integrated bone staple is used to provide fixation to the contralateral portion of the adjacent vertebral bodies.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Interwedge® Standalone Lateral is a standalone lateral lumbar interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L1-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The Interwedge® Standalone Lateral is to be filled with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone, and is to be used with
the two titanium alloy screws which accompany the implant. Should a physician choose to use
fewer than these two screws, additional supplemental fixation must be used to augment stability.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The submission are modifications to an existing device with an existing 510(k).

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices are near identical and the minor differences do not raise any new issues of safety and effectiveness. The predicate included in this submission is the earlier generation of the subject device. Specifically, the following characteristics are similar between the subject and predicates:

- Indications for Use
- Principle of Operation
- Structural Support Mechanism
- Materials of manufacture
- Range of Sizes

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

The Interwedge® Standalone Lateral has been tested in the following test modes to confirm equivalence to the predicate:

- Dynamic Axial Compression per ASTM F2077
- Dynamic Compression Shear per ASTM F2077
- Static Torsion per ASTM F077

The results of this non-clinical testing show that the strength of the Interwedge® Standalone Lateral is
sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.