October 2, 2024

Foundation Surgical Group, Inc.
℅ Hannah Taggart
Regulatory Associate
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K241487
Trade/Device Name: Interwedge® Standalone Lateral
Regulation Number: 21 CFR 888.3080
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: September 6, 2024
Received: September 6, 2024

Dear Ms. Taggart:

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,

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

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)*
K241487

Device Name
Interwedge® Standalone Lateral

Indications for Use *(Describe)*

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.

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

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K241487 510(K) SUMMARY

Submitter's Name:	Foundation Surgical Group, Inc.
Submitter's Address:	7327 E Tierra Buena Lane, Suite 101 Scottsdale, AZ 85260
Submitter's Telephone:	908-421-3971
Contact Person:	Hannah Taggart MS Empirical Technologies 1-719-457-1152 htaggart@empiricaltech.com
Date Summary was Prepared:	July 3, 2024
Trade or Proprietary Name:	Interwedge® Standalone Lateral
Device Classification Name:	Intervertebral Body Fusion Device with Integrated Fixation, Lumbar
Classification & Regulation #:	Class II per 21 CFR §888.3080
Product Code:	OVD
Classification Panel:	Orthopedic – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Interwedge® is a lateral standalone intervertebral body fusion device in the lumbosacral spine (L1-S1) intended to provide stability and promote fusion between adjacent vertebrae.

The Interwedge® consists of the intravertebral wedge (or spacer) with a lateral plate and a contralateral staple. The lateral plate, with two or four bones screw options, and the contralateral staple provide the integrated fixation to the construct. The Interwedge device is offered in a range of implant sizes and heights to cater to different patient anatomy. The spacer, lateral plate, and staple components will be additively manufactured from Ti-6Al-4 ELI per ASTM F3001. The sub-components of the staple mechanism and the integrated fixation screws will be machined from Ti-6Al-4V ELI per ASTM F136. A cover plate which is attached to the lateral plate after insertion of the bone screws is manufactured from Ti-6Al-4V ELI per ASTM F136.

INDICATIONS FOR USE

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.

TECHNOLOGICAL CHARACTERISTICS

The predicates included in this submission were selected based on the best practices described in the FDA Draft Guidance document *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. The subject and predicate devices have nearly identical technological characteristics and

the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are the same between the subject and predicates:

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

The differences between the subject device and the predicates, which include larger maximum AP width, maximum plate length, and the use of a contralateral staple for additional fixation, do not raise questions concerning safety and efficacy of the subject device since the subject device met performance testing requirements and the staple component is not a novel feature in FDA cleared lumbar spacers.

Predicate Devices

510k #	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K231743	F3D Lateral Lumbar Interbody System and Oro Plate	CoreLink, LLC	MAX, OVD	Primary
K152277	PIVOX™ Oblique Lateral Spine System	Medtronic Sofamor Danek USA, Inc.	MAX, OVD	Additional
K203714	NuVasive CoRoent Thoracolumbar System	NuVasive	MAX, PHM, OVD	Additional

PERFORMANCE DATA

The Interwedge® Standalone Lateral has been tested in the following test modes:

- Static and Dynamic Axial Compression per ASTM F2207
- Static and Dynamic Compression Shear per ASTM F2207
- Subsidence per ASTM F2267
- Expulsion testing
- Staple pull-apart testing
- Plate pull-apart testing
- Screw back-out testing
- ASTM F1877 particulate analysis of F2077 dynamic runouts

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.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Interwedge® Standalone Lateral is substantially equivalent to the predicate device.