November 7, 2024

Foundation Surgical Group, Inc.
% Nathan Wright, MS, RAC
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K241468
Trade/Device Name: Vertiwedge® Intraosseous System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: October 3, 2024
Received: October 3, 2024

Dear Mr. Wright:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241468

Device Name
Vertiwedge® Intraosseous System

Indications for Use *(Describe)*
The Vertiwedge® Intraosseous System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement of a diseased or damaged vertebral body resected or excised to replace a portion and/or restore the height of a collapsed vertebral body for the treatment of previous trauma (i.e, fracture or tumor) or degenerative spine disease. The system is to be placed within the vertebral body following an osteotomy and supplemented with autograft or allograft and to be used with its contralateral staple; should a physician choose to use fewer than the maximum number of screws, then supplemental fixation must be used to augment stability.

The Vertiwedge® Intraosseous System is intended to restore the integrity of the spinal column even in the absence of fusion in patients with advanced stage tumors involving the thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

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.

K241468 – 510(K) SUMMARY

Submitter's Name:	Foundation Surgical
Submitter's Address:	7327 E Tierra Buena Lane, Suite 101 Scottsdale, Arizona 85260
Submitter's Telephone:	727-209-7436
Contact Person:	Nathan Wright, MS, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	May 23, 2024
Trade or Proprietary Name:	Vertiwedge® Intraosseous System
Device Classification Name:	Spinal Vertebral Body Replacement Device
Classification & Regulation #:	Class II per 21 CFR §888.3060
Product Code:	MQP
Classification Panel:	Orthopedic – Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

Vertiwedge® Intraosseous System is an intraosseous device that is used as a motion-preservation partial vertebral replacement device in the thoracolumbar spine in the motion-sparing Vertebral Body Osteotomy (VBO®) procedure. The Vertiwedge® Intraosseous device is used within a single osteotomized vertebral body, and it does not span any disc levels nor involve resection of or interference with the discs. The Vertiwedge® Intraosseous device is implanted through an anterior to psoas/oblique approach following an osteotomy of the vertebral body, in a Vertebral Body Osteotomy (VBO®) procedure The Vertiwedge® Intraosseous System consists of the intraosseous wedge (or spacer) with a lateral plate and a unique staple that provides integrated contralateral fixation. The Vertiwedge® Intraosseous System 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 osteotomized vertebral wedges to aid in expulsion resistance. The Vertiwedge® Intraosseous System 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 and cover plate to provide fixation within the single impacted vertebral body. All implant components are manufactured from Ti-6Al-4V ELI per ASTM F3001 or ASTM F136.

INDICATIONS FOR USE

The Vertiwedge® Intraosseous System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement of a diseased or damaged vertebral body resected or excised to replace a portion and/or restore the height of a collapsed vertebral body for the treatment of previous trauma (i.e, fracture or tumor) or degenerative spine disease. The system is to be placed within the vertebral body following an osteotomy and supplemented with autograft or allograft and to be used with its contralateral staple; should a physician choose to use fewer than the maximum number of screws, then supplemental fixation must be used to augment stability.

The Vertiwedge® Intraosseous System is intended to restore the integrity of the spinal column even in the absence of fusion in patients with advanced stage tumors involving the thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have similar technological characteristics and the differences do not raise any new issues of safety and effectiveness. 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*. Specifically, the following characteristics are the same between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- General Design Features
    - Non-expandable spacer
    - Integrated Fixation without additional supplemental fixation
    - Screw Backout Prevention Plate
- Size Ranges
- Sterilization Methods

The differences between the subject and the predicates, which include 1) lateral integrated fixation without supplemental fixation rather than anterior integrated fixation without supplemental fixation, 2) coronal angulation for the spacer, and 3) the use of a contralateral staple for additional integrated fixation, do not raise any questions for safety and efficacy of the subject device since the subject device met performance testing requirements and because the coronal angulation and staple features are not novel features in FDA-cleared lumbar spacers.

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K081849	PILLAR SA PEEK Spacer System	Blackstone Medical, Inc.	OVD, MQP	Primary
K183071	VLIFT®-s Vertebral Body Replacement System	Stryker Spine	PLR, MQP	Additional
K171140	Matrixx System	Nexxt Spine LLC	ODP, MAX, MQP	Additional
K233359	Dominion Expandable Corpectomy System	Astura Medical	MQP, PLR	Additional
K220324	AccuFit Lateral Plate System	Precision Spine, Inc.	KWQ	Additional

PERFORMANCE DATA

The Vertiwedge® Interosseous System has been tested in the following test modes:

- ASTM F2077 static axial compression
- ASTM F2077 static compression shear
- ASTM F2077 static torsion
- ASTM F2077 dynamic axial compression
- ASTM F2077 dynamic compression shear
- ASTM F2077 dynamic torsion
- ASTM F1877 particulate analysis of F2077 dynamic runouts
- ASTM F2267 subsidence testing
- Expulsion testing
- Staple pull-apart testing
- Plate pull-apart testing

- Screw back-out testing
- Implantation testing

The results of this non-clinical testing show that the strength of the Vertiwedge® Interosseous System 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 Vertiwedge® Interosseous System is substantially equivalent to the predicate device.