April 29, 2021

Spectrum Spine, LLC
℅ Mr. Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K201024
Trade/Device Name: Expandable Titanium PLIF/TLIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 17, 2021
Received: March 18, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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 STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*
K201024

Device Name
Expandable Titanium PLIF/TLIF System

Indications for Use *(Describe)*

The Spectrum Spine Expandable PLIF/TLIF Interbody Cage System is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-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). Expandable PLIF/TLIF implants are to be filled with autogenous bone graft material. The device are intended to be used with 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.

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510(K) SUMMARY

Submitter's Name:	Spectrum Spine, LLC
Submitter's Address:	4020 Stovall Terrace NE Atlanta, GA 30342
Submitter's Telephone:	404-550-1335
Contact Person:	Nathan Wright Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	April 17, 2020
Trade or Proprietary Name:	Expandable Titanium PLIF/TLIF System
Common or Usual Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Division of Orthopedics

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Spectrum Spine Expandable Titanium PLIF/TLIF System consists of lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The Expandable Titanium PLIF/TLIF System implants are provided in various shapes to accommodate posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF) surgical approaches. These implants can expand to the desired height and varying degrees of lordosis as appropriate. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. The Expandable Titanium PLIF/TLIF System is to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

The Expandable Titanium PLIF/TLIF System is manufactured from titanium alloy per ASTM F136.

The system provides several footprints in multiple height and angle configurations. The cage's ability to be inserted at a nominal height and then expand in both height and angle to fill the joint space once properly positioned minimizes damage to the bony end-plate caused by impaction.

INDICATIONS FOR USE

The Spectrum Spine Expandable PLIF/TLIF Interbody Cage System is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-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). Expandable PLIF/TLIF implants are to be filled with autogenous bone graft material. The device are intended to be used with supplemental fixation.

TECHNOLOGICAL CHARACTERISTICS

The Expandable Titanium PLIF/TLIF System is made from medical grade titanium alloy that conforms to ASTM F136. The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Surgical Approach
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K172696	FORZA® XP Expandable Spacer System	Orthofix Inc.	Primary
K080537	L-Varlock Lumbar Cage	Kiscomedica	Additional
K173518	Spectrum Spine Expandable Cages	Spectrum Spine, LLC	Additional
K140411	ALTERA™ Spacer	Globus Medical, Inc.	Additional

PERFORMANCE DATA

The Expandable Titanium PLIF/TLIF System has been tested in the following test modes:

- Static axial compression per ASTM F2077
- Static compression shear per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Dynamic compression shear per ASTM F2077
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the Expandable Titanium PLIF/TLIF 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 Expandable Titanium PLIF/TLIF System is substantially equivalent to the predicate device.