December 16, 2019

Pantheon Spinal, LLC
Mr. Dave Lamb
3008 Bee Cave Road, Suite 200
Austin, Texas 78746

Re: K181548
Trade/Device Name: Pantheon Spinal Pontus Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 4, 2018
Received: June 12, 2018

Dear Mr. Lamb:

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, PhD
Assistant Director (Acting)
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K181548

Device Name

Pantheon Spinal Pontus Interbody Fusion System

Indications for Use *(Describe)*

The Pantheon Spinal Pontus Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. Pantheon Spinal Pontus Interbody Fusion Device is designed for use with autogenous bone graft to facilitate fusion. Pantheon Spinal Pontus Interbody Fusion Device is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. Pantheon Spinal Pontus Interbody Fusion Device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and lateral.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K181548 - 510(K) SUMMARY

Submitter: Pantheon Spinal, LLC

Address: 3008 Bee Cave Road, Suite 200, Austin, TX 78746 USA

Phone: 512-215 -4888

Contact Name: Dave Lamb

Date prepared: November 15, 2019

Trade Name: Pantheon Spinal Pontus Interbody Fusion Device

Common Name: Interbody Fusion Device

Device Classification: Class II

Regulation: 888.3080

Device Product Codes: MAX

Device Description:

The Pantheon Spinal Pontus Interbody Fusion Device is rectangular with one or more openings through the structure for placement of bone graft. The Epiphany device is hexahedral in geometry with two vertical openings. Pyramidal teeth are incorporated on the inferior and superior surfaces of each device. Tantalum markers provide visual feedback with respect to the invivo implant position. An articulating hub provides adjustable angulation of the device with respect to the inserter shaft. The devices are available in a variety of sizes offered in widths 18-24mm (2mm increments), in lengths 40-60mm (5mm increments), heights 8-16mm (2 mm increments), in 0, 7 and 12 degree lordosis to accommodate differing anatomic requirements.

Intended Use:

Pantheon Spinal Pontus Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. Pantheon Spinal Pontus Interbody Fusion Device is designed for use with autogenous bone graft to facilitate fusion. Pantheon Spinal Pontus Interbody Fusion Device is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. Pantheon Spinal Pontus Interbody Fusion Device is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches include anterior and lateral.

Materials:

PEEK Zeniva ZA 500 with markers of Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400) and a hub of Titanium Alloy Ti-6AL-4V

Primary Predicate Device:

The Pantheon Spinal Interbody Fusion Device (K113781)

Additional Predicate Devices

Summit Spine Yellowstone Lumbar Interbody Fusion System (K170572)

Technological Characteristics

The Pantheon Spinal Interbody Fusion System possesses the same technological characteristcs as the predicate devices including basic design, with various footprints and lordosis, sizes (length, height, width) materials, mechanical safety and performances, and intended use.

Performance Data

Biomechanical test results demonstrated that the Pantheon Spinal Interbody Fusion Device is equivalent to the predicate devices. Testing was performed in accordance with :

- ASTM F2077 Test Methods for Intervertebral Body Fusion Devices
  - o Static Axial Compression
  - o Dynamic Axial Compression
  - o Static Compression Shear
  - o Dynamic Compression Shear
- ASTM F2267 Standard Test Method for Measuring Load Induced Subsidence of an intervertebral Body Fusion Device Under Static Axial Compression

Conclusion:

The Pantheon Spinal Interbody Fusion System devices ae similar to the predicate systems with respect to technical characteristics, performance and intended use. The information provided in this premarket notification supports substantial equivalend of the subject device to the predicate device