July 7, 2021

Pantheon Spinal
Dave Lamb
Quality and Regulatory Affairs
40132 Industrial Park Circle Suite 101
Georgetown, Texas 78626

Re: K203003
Trade/Device Name: Pantheon IBFD
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 9, 2021
Received: June 10, 2021

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 L. 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)*
K203003

Device Name
Pantheon IBFD

Indications for Use *(Describe)*
When used as an intervertebral fusion device, the Pantheon IBFD devices are intended for use as either one level or two contiguous levels in the lumbar spine from L2 to S1, for the treatment of 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 device is to be used in patients who are skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. The devices are intended for use with supplemental fixation cleared for use in the lumbar spine and with autograft to facilitate 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.

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510(k) Summary

Date: July 6, 2021

Sponsor: Pantheon Spinal
40132 Industrial Park Circle Suite
101 Georgetown, TX 78626
512-308-3488

Establishment Registration 3010665091

Sponsor Contact: Dave Lamb

Proposed Trade Name: Pantheon IBFD

Common Name: Interbody Fusion System

Device Classification: Class II

Regulation Name Intervertebral fusion device
Product Code MAX
Regulation Number 888.3080

Primary Predicate: Pantheon Spinal Interbody Fusion Device K181548, K113781

Additional Predicates Titan Spine Endoskeleton TL Hyperlordotic Interbody Fusion Device K191581

Device Description: The Pantheon IBFD is oval in shape with one or more openings through the structure. 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 to accommodate differing anatomic requirements. The device is manufactured from medical grade PEEK in accordance with ASTM F2026 and Ti6Al4V titanium alloy with tantalum markers conforming to ASTM F136. The subject device introduces the 20 degree hyperlordotic sizes in a variety of lengths, widths and heights.

Indications for use: When used as an intervertebral fusion device, the Pantheon IBFD devices are 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 I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who are skeletally mature and have had six months of non- operative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. The devices are intended for use with supplemental fixation cleared for use in the lumbar spine and with autograft to facilitate fusion.

Substantial Equivalence: The Pantheon IBFD is substantially equivalent to the primary predicate Pantheon Spinal Interbody Fusion Device (K181548) with respect to design, function, intended use, and materials with the exception of the proposed additional sizes.

Pantheon Spinal Interbody Fusion Device K181548 and additional (secondary) predicate Titan Spine Endoskeleton TL Hyperlordotic Interbody Fusion Device K191581 are similar in design,materials, and indications. The new Pantheon IBFD does not raise new questions about safety and effectiveness.

Performance Testing: **N**ew ASTM F2077 static and dynamic compression tests were performed to validate changes to the device. An FEA was created to verify that a new worse case was not created with the new size additions.

Conclusion: Based on information contained in this submission, and the similarities of the subject and predicate devices, the subject IBFD Interbody Fusion System is substantially equivalent to the predicate devices.