December 21, 2017

Tyber Medical, LLC
Mark F. Schenk
Vice President of Regulatory and Quality
83 South Commerce Way, Suite 310
Bethlehem, Pennsylvania 18017

Re: K172185
Trade/Device Name: Tyber Medical PT Interbody Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: November 7, 2017
Received: November 15, 2017

Dear Mr. Schenk:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172185

Device Name
Tyber Medical PT Interbody Spacer System

Indications for Use *(Describe)*

Lumbar System Indications

The Tyber Medical PT Interbody System is indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior, transforaminal, lateral or anterior approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.

Cervical System Indications

The Tyber Medical PT Interbody System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. Cervical implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, supplemental fixation must be used.

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:

TYBER MEDICAL PT Interbody Spacer System
K172185

Submitted by	Tyber Medical, LLC 83 South Commerce Way Suite 310 Bethlehem, PA 18017
Contact Person	Mark F. Schenk Vice President of Regulatory and Quality Phone: (610) 849-0645 Fax: (866) 889-9914 Email: mschenk@tybermed.com
Date Prepared	December 19, 2017
Common Names	Interbody Spacer System
Trade Name	Tyber Medical PT Interbody Spacer System
Classification Name and Number	Intervertebral body fusion device (21 CFR 888.3080)
Product Code	ODP and MAX
Predicate Device	Tyber Medical Interbody Spacer System (K130573)
Additional Predicates	Synthes ACIS (K120275), DePuy Spine Concorde Curve (K101923), DePuy Spine Lateral System (K090899); Aesculap ASpace, CESpace, Prospace, T-Space (K071983)
Device Description	This submission is to add additional shape configurations, with an optional optimized coating process, to the previously cleared interbody system. This submission does not include any new instruments. However, part of the changes to implants, were made to interface with instruments that were cleared with previous submissions. The Tyber Medical PT Interbody System, manufactured from PEEK-Optima®, consist of implants available in various foot prints, heights, and lordotic configurations with an open architecture to accept packing of bone graft materials. The exterior of the device has "teeth" or other generally sharp engagement members on the superior and inferior surfaces to help prevent the device from migrating once it is surgically positioned. The device comes in PEEK with a plasma-sprayed commercially pure titanium coating.

Intended Use/ Indications for use	Lumbar System Indications The Tyber Medical PT Interbody System is indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a posterior, transforaminal, lateral or anterior approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine. Cervical System Indications The Tyber Medical PT Interbody System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. Cervical implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, supplemental fixation must be used.
Performance Data (Non-Clinical)	The following tests were performed on the Tyber Medical PT Interbody Spacer and the results were compared to with the previously cleared 510k K130573. • Static and Dynamic Compression Test per ASTM F2077 • Static and Dynamic Compression Shear per ASTM F2077 • Wear Debris per ASTM F2077 and ASTM F1877 • Static Torsion per ASTM F2077 • Pyrogenicity testing was performed per ST72:2011.
Performance Data (Clinical)	Clinical data and conclusions were not needed for this device.
Statement of Technological Comparison	The Tyber Medical PT Interbody System and its predicate devices have the same indications for use, same design, are made of identical materials, identical application, and have the same anatomic mechanical properties.
Conclusion	The new Tyber Medical PT Interbody System is substantially equivalent to the predicate device because the material, tooth profile, worst case construct, smallest cross sectional and manufacturing process are all unchanged. The addition of the new interbody device does not add a new worst-case device for mechanical testing purposes, as demonstrated by mechanical test results. Given the above, Tyber Medical PT Interbody System is determined to be substantially equivalent to the predicate device.