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

July 6, 2018

Re: K180590
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: June 4, 2018
Received: June 8, 2018

Dear Mark 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 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,

Brent Showalter -S

for
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)*
K180590

Device Name
Tyber Medical PT Interbody Spacer System

Indications for Use *(Describe)*

Cervical System Indications:

The Tyber Medical PT Interbody Spacer 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 and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as an interbody fusion device, supplemental fixation must be used.

Lumbar System Indications:

The Tyber Medical PT Interbody Spacer 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). DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may also have had a previous non-fusion spinal surgery at the involved spinal level(s). Additionally, the Tyber Medical PT Interbody System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. Patients should have six weeks 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 autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.

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

K180590

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	July 6, 2018
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, Class II)
Product Code	ODP and MAX
Primary Predicate Device	Tyber Medical PT Interbody Spacer System (172185)
Additional Predicates	DPS Concorde Bullet Lumbar Interbody (K151773), Aesculap Plasmapore XP Spinal System (K132421), DPS T-PAL Spacer System (K162358) and Medtronic Anatomic PEEK PTC Cervical Fusion System (K133653).
Device Description	This submission is to update language in the Indications for Use, and update language in the package insert in reference to MR testing. There is no change with this submission from the primary predicate. This submission does not change or add any new instruments. The Tyber Medical PT Interbody System, manufactured from PEEK-Optima® LT1, with a plasma-sprayed integrated commercially pure titanium. The system consists 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.

Intended Use/ Indications for use	**Cervical System Indications**: The Tyber Medical PT Interbody Spacer 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 and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as an interbody fusion device, supplemental fixation must be used. **Lumbar System Indications**: The Tyber Medical PT Interbody Spacer 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). DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may also have had a previous non-fusion spinal surgery at the involved spinal level(s). Additionally, the Tyber Medical PT Interbody System can be used in patients diagnosed with spinal deformities as an adjunct to fusion. Patients should have six weeks 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 autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.
Performance Data (Non-Clinical)	No new mechanical testing was performed, because there is no change to the device. MR testing was performed per ASTM F2052-15, ASTM F2119-07, ASTM F2213-06, ASTM F2503-13 & ASTM F2182-11a.
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. There is no change in design, materials, or mechanical properties from the primary predicate. The Tyber Medical PT Interbody System has similar design, materials, and mechanical properties to the additional predicate devices.
Conclusion	The Tyber Medical PT Interbody System is substantially equivalent to the predicate device because it has similar indications for use, and the design, materials, application, manufacturing process, and anatomic mechanical properties are all unchanged. The Tyber Medical PT Interbody System is substantially equivalent to the additional predicate devices because the materials, indications, product code, application, range of sizes, and designs are similar.