Traditional 510(k) Summary

TYBER MEDICAL PT Interbody Spacer System
K182284

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	January 16, 2019
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
Primary Predicate	Tyber Medical PT Interbody System (K180590),
Additional Predicate Devices	Nuvasive (K163491), Globus (K173722), Tyber Medical Interbody System (K130573) and Tyber Medical PT Interbody Line Extension (K172185)
Device Description	This submission is to add additional ACIF configurations to the Tyber Medical PT Interbody System and corresponding trials. Additionally, the Indications for Use are being revised. The new configurations will be manufactured from PEEK – Optima® and plasma sprayed with commercially pure titanium coating, identical to the existing devices in the system. The new ACIF configurations have superior and inferior surfaces that are inclined at larger angles than the existing configurations. In addition, a new extra-large configuration for these sizes will be included. Other geometries, such as the open lumen area and teeth geometry on the superior and inferior surfaces remain identical to the devices within the Tyber Medical PT Interbody System. The trials will be manufactured from stainless steel and will incorporate trial geometries that match the corresponding implant.

Intended Use/ Indications for use	**<u>Cervical System Indications</u>**: The Tyber Medical PT Cervical Interbody Spacers are interbody fusion devices indicated at one or more levels of the cervical spine C2-T1 in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. Tyber Medical PT Cervical Interbody spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. These devices are intended to be used with supplemental fixation.
Performance Data (Non-Clinical)	The following tests were performed on the Tyber Medical PT Interbody Spacer and the results were compared to the previously cleared 510k K130573. • Static and Dynamic Compression Test per ASTM F2077 • Static and Dynamic Compression Shear per ASTM F2077 • Static and Dynamic Torsion per ASTM F2077 • Expulsion Testing • 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 design; are made of identical materials, have similar applications, and indications, and have equivalent anatomic mechanical properties.

Conclusion	The new configurations are substantially equivalent to the devices in the Tyber Medical PT Interbody System, based on design, material, indications and test results. Additionally, the Tyber Medical PT Interbody devices are similar in design and material to the additional predicate devices. The Tyber Medical PT Interbody devices included in this submission, do not raise any additional risk to safety and effectiveness.

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)*
K182284

Device Name
Tyber Medical PT Interbody Spacer System

Indications for Use *(Describe)*
Cervical System Indications:
The Tyber Medical PT Cervical Interbody Spacers are interbody fusion devices indicated at one or more levels of the cervical spine C2-T1 in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment.

Tyber Medical PT Cervical Interbody spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. These devices 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.

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

February 25, 2019

Re: K182284
Trade/Device Name: Tyber Medical PT Interbody Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: December 13, 2018
Received: December 18, 2018

Dear Mark Schenk:

This letter corrects our substantially equivalent letter of January 18, 2019.

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure