DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 1, 2016

Met 1 Technologies, LLC
% Mr. Kenneth C. Maxwell II
Regulatory and Quality Specialist
Empirical Testing Corporation
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K160699
Trade/Device Name: VIRTU Lumbar Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 23, 2016
Received: June 27, 2016

Dear Mr. Maxwell:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160699

Device Name
VIRTU Lumbar Spacer System

Indications for Use *(Describe)*
The VIRTU Lumbar Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1) with up to Grade 1 spondylolisthesis or retrolisthessis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the VIRTU Lumbar Spacer System.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the VIRTU PLIF/TLIF System.

The VIRTU Lumbar Spacer System is designed for use with autogenous bone graft to facilitate fusion. The system is also intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Submitter's Name:	Met 1 Technologies, LLC
Submitter's Address:	154 N. Festival Dr., Ste. F El Paso, TX 79912
Submitter's Telephone:	915.301.0834
Contact Person:	Kenneth C. Maxwell II Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	22 July 2016
Trade or Proprietary Name:	VIRTU Lumbar Spacer System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080 Device Classification
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The VIRTU Posterior Lumbar Spacer System consists of implants, trials and instruments. The VIRTU Lumbar Spacer System may be implanted bilaterally using a posterior (PLIF) approach, or as a single device employing a transforaminal (TLIF) approach.

INDICATIONS FOR USE

The VIRTU Lumbar Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1) with up to Grade 1 spondylolisthesis or retrolisthessis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the VIRTU Lumbar Spacer System.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the VIRTU PLIF/TLIF System.

The VIRTU Lumbar Spacer System is designed for use with autogenous bone graft to facilitate fusion. The system is also intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

The indications for use for the VIRTU Lumbar Spacer System is similar to that of the predicate devices listed in table 5-1.

TECHNOLOGICAL CHARACTERISTICS

All implant components are manufactured from PEEK per ASTM F2026 and tantalum per ASTM F560. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of Manufacture
- Structural Support Mechanism
- Principles of Operation

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K122097	PATRIOT™ Spacers	Globus Medical Inc.	Primary
K130573	Interbody System	Tyber Medical	Additional
K112095	AccuLiF® TL-PEEK Cage and AccuLiF® TL and PL	CoAlign Innovation	Additional
K113478	PLIF Cage	Eisertech	Additional

PERFORMANCE DATA

The VIRTU Lumbar Spacer System has been tested in the following test modes:

- Static axial compression per modified ASTM 2077-11
- Dynamic axial compression per ASTM 2077-11
- Expulsion per ASTM Draft Standard F-04.25.02.02
- Subsidence per ASTM F2267

The results of this non-clinical testing show that the strength of the VIRTU Lumbar Spacer System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the VIRTU Lumbar Spacer System is substantially equivalent to the predicate device.