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

November 9, 2016

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

Re: K161649
Trade/Device Name: Virtu C Spinal Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MQP
Dated: October 3, 2016
Received: October 6, 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" (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.

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,

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 on last page.

510(k) Number *(if known)*
K161649

Device Name
Virtu C Spinal Implant

Indications for Use *(Describe)*

When used as an Intervertebral Body Fusion Device:
The Virtu C cervical spine devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine (C2-T1). The Virtu C device is intended to be used with autograft and/or allograft bone (allogenic bone graft comprised of cancellous and/or corticocancellous bone graft). The Virtu C device is intended to be used with a FDA cleared cervical supplemental fixation system. Patients should receive 6 weeks of non-operative treatment prior to treatment.

When used as a Vertebral Body Replacement Device:
The Virtu C device is indicated for use in the thoracolumbar spine (T1-L5) for partial or total replacement of a damaged, collapsed or unstable vertebral body due to trauma/fracture or tumor to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Virtu C device is intended to be used with autograft and/or allograft bone. The Virtu C device is intended to be used with a FDA cleared supplemental fixation device such as a lumbar pedicle screw system.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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:	09 November 2016
Trade or Proprietary Name:	Virtu C Spinal Implant
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Cervical Spinal Vertebral Body Replacement System
Classification:	Class II per 21 CFR §888.3080 Class II per 21 CFR §888.3060
Product Code:	ODP, MQP
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Met 1 Technologies Virtu C Spinal Intervertebral Body Fusion Device is a cervical intervertebral body fusion device that is implanted into the invertebral body space to improve stability of the spine while supporting fusion. A variety of implant sizes are provided to accommodate individual patient anatomy. The implants are manufactured from VESTAKEEP® i4 R PEEK per ASTM F2026 and have tantalum markers per ASTM F560.

The Met 1 Technologies Virtu C Spinal Vertebral Body Replacement Device is a thoracolumbar vertebral body replacement device that is implanted to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. A variety of implant sizes are provided to accommodate individual patient anatomy. The implants are manufactured from VESTAKEEP® i4 R PEEK per ASTM F2026 and have tantalum markers per ASTM F560.

INDICATIONS FOR USE

When used as an Intervertebral Body Fusion Device:

The Virtu C cervical spine devices are indicated for use in skeletally mature patients with degenerative disc disease (DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine (C2-T1). The Virtu C device is intended to be used with autograft and/or allograft bone (allogenic bone graft comprised of cancellous and/or corticocancellous bone graft). The Virtu C device is intended to be used with a FDA cleared cervical supplemental fixation system. Patients should receive 6 weeks of non-operative treatment prior to treatment.

When used as a Vertebral Body Replacement Device:

The Virtu C device is indicated for use in the thoracolumbar spine (T1-L5) for partial or total replacement of a damaged, collapsed or unstable vertebral body due to trauma/fracture or tumor to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Virtu C device is intended to be used with autograft and/or allograft bone. The Virtu C device is intended to be used with a FDA cleared supplemental fixation device such as a lumbar pedicle screw system.

TECHNOLOGICAL CHARACTERISTICS

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 similar between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Principle of operations

Table 5-1: Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K112036	Calix™ Spinal Implant System	X-Spine Systems	Primary
K083637	Calix™ Spinal Implant System	X-Spine Systems	Reference
K142205	X-CORE® Expandable VBR System	NuVasive	Reference

PERFORMANCE DATA

The Virtu C Spinal Implant System has been tested in the following test modes and demonstrated substantial equivalence:

- Static axial compression per ASTM F2077
- Static torsion per ASTM F2077
- Static subsidence per ASTM F2267
- Static expulsion per ASTM F-04.25.02.02
- Dynamic axial compression per ASTM F2077
- Dynamic torsion per ASTM F2077

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Virtu C Spinal Implant System is substantially equivalent to the predicate device.