DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 2, 2017

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

Re: K170108
Trade/Device Name: Xultan 5.5 Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: January 12, 2017
Received: April 6, 2017

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,

Vincent J. Devlin -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)*
K170108

Device Name

Xultan 5.5 Pedicle Screw System

Indications for Use *(Describe)*

The Xultan 5.5 Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. The Xultan 5.5 Pedicle Screw System is intended for posterior, pedicle fixation as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine (T1-S2/ilium); degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvature (i.e., scoliosis, kyphosis and/or lordosis); tumor; and failed previous fusion (i.e., pseudoarthrosis).

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

Submitter's Name:	Met One Technologies
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:	05 April 2017
Trade or Proprietary Name:	Xultan 5.5 Pedicle Screw System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070 Device Classification
Product Code:	NKB
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Xultan 5.5 Pedicle Screw System is an implant device manufactured from titanium and silicone. The screws are available cannulated or non-cannulated in various diameters and lengths to accommodate various patient anatomies. The system includes straight rods, curved rods, crosslinks, and associated instrumentation.

INDICATIONS FOR USE

The Xultan 5.5 Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients. The Xultan 5.5 Pedicle Screw System is intended for posterior, pedicle fixation as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine (T1-S2/ilium): degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvature (i.e. scoliosis, kyphosis and/or lordosis); tumor; and failed previous fusion (i.e. pseudoarthrosis).

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 identical between the subject and predicates:

- Indications for use
- Structural support mechanism
- Principles of operation

Table 5-1: Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K000236	International Synergy™ VLS	INTERPORE CROSS	Primary
K111940	S 100 PSS	Renovis	Additional
K143163	AVS® Cage Spacer	Stryker	Reference

PERFORMANCE DATA

The Xultan 5.5 Pedicle Screw System has been tested in the following test modes:

- Static axial compression bending per ASTM F1717-15
- Static torsion per ASTM F1717-15
- Dynamic axial compression bending per ASTM F1717-15

The results of this non-clinical testing show that the strength of the Xultan 5.5 Pedicle Screw 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 Xultan 5.5 Pedicle Screw System is substantially equivalent to the predicate device.