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

October 7, 2016

Providence Medical Technology, Inc.
Mr. Edward Liou
Chief Operating Officer
1331 North California Boulevard, Suite 320
Walnut Creek, California 94596

Re: K161642
Trade/Device Name: CAVUX™ Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: September 7, 2016
Received: September 9, 2016

Dear Mr. Liou:

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 Parts 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,

Mark N. Melkerson -S

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)*
K161642

Device Name
CAVUX™ Cervical Cage

Indications for Use *(Describe)*
CAVUX™ Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-C7) with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be used with autogenous bone graft and supplemental fixation, such as an anterior plating 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Providence Medical Technology, Inc.'s CAVUX™ Cervical Cages

Date Prepared: September 7, 2016

Company: Providence Medical Technology, Inc.
1331 N. California Blvd., Suite 320
Walnut Creek, CA 94596

Contact Person: Edward Liou
ed@providencemt.com
Phone: 415.923.9376
Facsimile: 415.923.9377

Trade Name: CAVUX™ Cervical Cage

Common Name: Cervical Cage

Classification Name: Intervertebral Fusion Device With Bone Graft, Cervical

Regulation Number: 21 CFR 888.3080

Product Code: ODP
Class: Class II

Predicate Devices:

Primary Predicate: PMT Cervical Cage (K122801, Cleared 5/24/13)
(This device has not been subject to recall.)

Reference Device: Titan Spine, LLC: Endoskeleton® TC
(K100889, Cleared 7/29/10)

Device Description:

The CAVUX™ Cervical Cage is a cervical intervertebral body fusion device. The system is comprised of a variety of implant sizes to accommodate various patient anatomies and pathology. All implantable components are manufactured from medical grade titanium alloy (6Al4V –ELI Ti). The center of the implant is hollow and is to be filled with autogenous bone material. The design incorporates "windows" through the implant to permit visualization of the graft material and, over time, formation of new bone.

Indications for Use:

CAVUX™ Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-C7) with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least six weeks of non-operative treatment prior to treatment with the device. Devices are intended to be used with autogenous bone graft and supplemental fixation, such as an anterior plating system.

Technological Characteristics:

The CAVUX™ Cervical Cage consists of the following:

- CAVUX™ Cervical Cage Implant
- Delivery Instrument packaged with the Implant

The CAVUX™ Cervical Cage implants are manufactured from Titanium-6AL-4V ELI alloy, which conforms to ASTM F136 and are available in a variety of sizes and lordotic angles to accommodate patient anatomy. Superior and inferior surfaces of the implant feature teeth that provide bony contact with the endplates while a box shape in the center of the implant with fenestrations (windows) is intended to house autogenous bone. The superior and inferior surfaces of the implant are grit blasted and acid etched to improve fixation to adjacent bone.

The CAVUX™ Cervical Cage is held within the delivery instrument which facilitates insertion of the implant into the interbody space. The delivery instrument features a physical stop to prevent over-insertion.

Devices are supplied sterile and single use only.

Performance Testing

The following testing was performed using the subject device and results were compared to those of the predicate device:

Static and Dynamic Axial Compression Testing

- ASTM F2077-14 Standard Test methods for Intervertebral Body Fusion Devices

Static and Dynamic Torsion Testing

- ASTM F2077-14 Standard Test methods for Intervertebral Body Fusion Devices

Subsidence Testing

- ASTM F2267-04 Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression

Expulsion Testing

- ASTM Draft Standard F-04.25.02.02 *Static Push-out Test Method for Intervertebral Body Fusion Devices*

Pyrogenicity Testing

- Pyrogenicity Testing was conducted and in compliance with FDA Guidance Documents listed below:
  - "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile: Guidance for Industry and Food and Drug Administration Staff"
  - "Pyrogen and Endotoxins Testing: Questions and Answers"

In all instances, the CAVUX™ Cervical Cage functioned as intended and met all pre-determined acceptance criteria. Bench testing results of the CAVUX™ Cervical Cage exceeded those of the predicate PMT Cervical Cage. Therefore, the performance characteristics of the CAVUX™ Cervical Cage are substantially equivalent to those of the PMT Cervical Cage.

Conclusions

The CAVUX™ Cervical Cage has the same indication for use, technological characteristics, and principles of operation as the predicate device. The differences between the subject and predicate devices are that the subject device includes a surface treatment and is available in different sizes than the predicate device. These minor differences between the CAVUX™ Cervical Cage and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the CAVUX™ Cervical Cage is as safe and effective as the PMT Cervical Cage. Thus, the CAVUX™ Cervical Cage is substantially equivalent to the PMT Cervical Cage.