PMT Cervical Cage
510(k) Summary of Safety and Effectiveness

MAY 2 4 2013

Submitted By:	Providence Medical Technology, Inc. 201 Spear Street, Suite 1310 San Francisco, CA. 94105 Tel: (415) 923-9376 Fax: (415) 923-9377
Establishment Registration Number:	3009394448
Contact Person:	Edward Liou ed@providencemt.com Tel: (415) 923-9376
Date Summary Prepared:	17 May 2013
Trade Name:	PMT Cervical Cage
Common Name:	Cervical Cage
Device Classification Regulation:	21 CFR §888.3080 – Class II
Device Product Code & Panel:	ODP: Intervertebral Fusion Device With Bone Graft, Cervical 87, Orthopedics
Predicate Device(s):	Zimmer BAK®/C (P980048B) Wenzel VariLift-C (K111123) RSB Spine Interplate C (K092070) Signur Rabea Ti (K082848) Medyssey C7 Anterior Cervical Cage (K121320)

Device Information

A. Intended Use

PMT 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.

B. Device Description

The PMT Cervical Cage is an intervertebral fusion device intended to be used in cervical spinal fusion surgery. It provides mechanical support to the spine and has the following design features:

- Devices are single use and supplied sterile.
- Rectangular box shape with fenestrations (graft windows).
- Superior and inferior surfaces feature teeth that provide bony contact with the endplates.
- Manufactured from Titanium-6AL-4V ELI alloy, conforming to ASTM F136
- Available in various footprints and heights.

C. Substantial Equivalence Information

The performance, design, materials used, and intended use of the PMT Cervical Cage are substantially equivalent to previously cleared predicate devices.

D. Non-Clinical Test Summary

- Static and Dynamic Compression Testing was conducted per ASTM F2077-11
- Static and Dynamic Torsion Testing was conducted per ASTM F2077-11
- Subsidence testing was conducted per ASTM F2267-04
- Expulsion testing was conducted per ASTM Draft Standard F-04.25.02.02, (ASTM, 2000)

PMT Cervical Cage met or exceeded the performance of predicate devices on these tests. Based on these results, PMT Cervical Cage is substantially equivalent to the predicate devices.

E. Conclusions

PMT Cervical Cage has the same intended use, design, materials, performance and function of predicate devices. In conjunction with the mechanical testing, PMT Cervical Cage device has been shown to be substantially equivalent to the predicate devices and is safe and effective for its intended use.

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

May 24, 2013

Providence Medical Technology, Incorporated
% Mr. Edward Liou
Director of Engineering
201 Spear Street, Suite 1310
San Francisco, California 94105

Re: K122801
Trade/Device Name: PMT Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: March 18, 2013
Received: March 21, 2013

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

For Erin D. Keith

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

Enclosure

Indications for Use

510(k) Number (if known): K122801

Device Name: PMT Cervical Cage

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices