K090707

PREMARKET NOTIFICATION 510(K) SUMMARY

JUL 15 2009

Company:

Company Name	Meditech Advisors, LLC
Street address	878 Briarcliff Rd, Unit A-2
City, State, Zip Code	Atlanta, GA 30306
Telephone	404-879-0993

Company Contact: Eric Flickinger

Common Name Interbody fusion device

Trade Name: Talos™ Intervertebral Body Fusion (IBF) Device

Classification/Code: Class II, MAX, 888.3080

Device Description: The Talos™ IBF Device is made of PEEK-OPTIMA®. The Talos™ IBF Device is available in four configurations: Talos™-P, Talos™-T, Talos™-L, and Talos™-A. The devices are open devices with ridged teeth on superior and inferior ends to resist implant pullout. The Talos™-P and Talos™-L are rectangular devices and the Talos™-T and Talos™-A have curved lateral walls and rounded edges. The implants are available in a range of sizes, as well as flat and lordotic angled implants, to accommodate variations in patient's anatomy. In addition, tantalum markers at the opposite ends are offered which allow the Talos™ IBF radiological confirmation for proper positioning.

Intended Use: The Talos™ IBF Device is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Talos™ IBF devices are intended to be used with autologous bone graft to facilitate fusion. The Talos™ IBF device is to be used in patients who have had six months of non-operative treatment. Talos™ IBF devices are to be implanted via a direct posterior, transforaminal, lateral or anterior approach. The Talos™-P device is implanted in pairs, while the Talos™-A, Talos™-L and Talos™-T devices may be implanted singly or in pairs in the lumbosacral spine. The Talos™-A, Talos™-L, Talos™-P, and Talos™-T are intended to be used with supplemental fixation.

Performance Data: Talos™ IBF devices conforms to Class II Special Controls Guidance Document: Intervertebral Body Fusion Devices, June 12, 2007. Mechanical testing was conducted per ASTM F 2077-03 and ASTM F 2267-04.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2009

Meditech Advisors, LLC
c/o Ms. Janet Webb
President
950 N. Michigan Ave., Suite 2202
Chicago, Illinois 60611

Re: K090707
Trade/Device Name: Talos Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 29, 2009
Received: June 2, 2009

Dear Ms. Webb:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Melkerson for

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

Enclosure

Indication for Use Statement

510(k) Number : K090707

Device Name: Talos™ Intervertebral Body Fusion Device

Indications for Use:

The Talos™ IBF Device is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbar spine with up to Grade 1 spondylolisthesis at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Talos™ IBF devices are intended to be used with autologous bone graft to facilitate fusion. The Talos™ IBF device is to be used in patients who have had six months of non-operative treatment.

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Prescription Use ___X___ or Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for MXM)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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