**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2017

Meditech Spine, LLC
Bruce Dunaway
Chief Design Engineer
1447 Peachtree Street NE Suite 440
Atlanta, Georgia 30309

Re: K170395
Trade/Device Name: Talos® Lumbar (HA) PEEK IBF Devices
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 4, 2017
Received: March 8, 2017

Dear Mr. Dunaway:

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)*
K170395

Device Name
Talos® Lumbar (HA) PEEK IBF Devices

Indications for Use *(Describe)*

The Talos® Lumbar (HA) PEEK 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® Lumbar (HA) PEEK IBF devices are intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The Talos® Lumbar (HA) PEEK IBF Device is to be used in patients who have had six months of non- operative treatment.

Talos® Lumbar (HA) PEEK IBF devices are to be implanted via a direct posterior, transforaminal, lateral, anterior or anteriolateral approach in the lumbosacral spine. The Talos®-P (HA), Talos®-P WB (HA), Talos®-TL (HA), Talos®-T (HA), Talos®-L (HA), and Talos®-A (HA) are intended to be used with supplemental fixation.

Additionally, the use of Hyperlordotic Talos®-A (HA) devices (lordotic angle greater than 20°) are intended to be used exclusively with anterior supplemental fixation.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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meditech spine, llc.

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# 510(k) Summary

*As required by section 807.92(c)*

Meditech Spine, LLC is requesting marketing clearance for the Talos® Lumbar (HA) PEEK IBF.

A. Sponsor/Manufacturer: Meditech Spine, LLC
Registration Number: 3009405289
Bruce Dunaway, Chief Design Engineer
1447 Peachtree St NE Suite 440
Atlanta, GA 30309
678-974-5287 Phone
404-759-2104 Fax

B. Trade Name: Talos® Lumbar (HA) PEEK IBF Devices

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral body fusion device (21 CFR 888.3080 Class II, Product Code MAX)

C. Predicate Devices: K 150788: Meditech Spine, LLC Talos® Intervertebral Body Fusion Devices (Primary)
K090707: Meditech Advisors, LLC Talos® Intervertebral Body Fusion Devices (Additional)

D. Device Description:

The Talos® Lumbar (HA) PEEK IBF Devices are made of the polymer, hydroxyapatite impregnated polyetheretherketone (HA PEEK). The Talos® Lumbar (HA) PEEK IBF Device is available in six configurations: Talos®-P (HA), Talos®-P WB (HA), Talos®-T (HA), Talos®-TL (HA), Talos®-L (HA), and Talos®-A (HA). The devices are open devices with ridged teeth on superior and inferior ends to resist implant pullout. The Talos® –P (HA), Talos® –P WB (HA), Talos® –TL (HA) and Talos® –L are rectangular devices. The Talos® –T (HA) and Talos® – A (HA) 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 anatomy. In addition, tantalum or titanium markers at the opposite ends are offered which allow radiological confirmation for proper IBF positioning.

E. Intended Use:

Talos® Lumbar (HA) PEEK IBF Devices are intervertebral body devices 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.

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Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Talos® Lumbar (HA) PEEK IBF Devices are intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The Talos® Lumbar (HA) IBF PEEK Device is to be used in patients who have had six months of non- operative treatment.

Talos® Lumbar (HA) PEEK IBF Devices are to be implanted via a direct posterior, transforaminal, lateral, or anterior approach in the lumbosacral spine. The Talos®-A (HA), Talos®-L (HA), Talos®-P (HA), Talos®-P WB (HA), Talos®- T (HA) and Talos®- TL (HA) are intended to be used with supplemental fixation.

Additionally, the use of Hyperlordotic Talos®-A (HA) devices (lordotic angle greater than 20°) are intended to be used exclusively with anterior supplemental fixation.

F. Technological Characteristics:

The technological characteristics of the Talos® Lumbar (HA) PEEK IBF devices are identical to the predicate devices in terms of indications for use and intended use. Size offerings and choices of lordotic angles have been expanded for the Talos® Lumbar (HA) PEEK IBF Devices. The significant difference between the Talos® Lumbar (HA) PEEK IBF Devices and the predicate is in material composition: hydroxyapatite impregnated polyetheretherketone (HA PEEK) vs. polyetheretherketone (PEEK)

G. Non-clinical Testing:

Testing per ASTM F2077 (Static Compression, Static Compression Shear, Dynamic Compression, Dynamic Compression Shear) and ASTM F2267 (Subsidence) was performed on the Talos® Lumbar (HA) PEEK IBF devices to establish equivalency to the predicate device. Confirmation was achieved that the Talos® Lumbar (HA) PEEK IBF devices are substantially equivalent in safety and efficacy to the predicate device. In addition, bacterial endotoxin testing (BET) has been performed. BET as specified in ANSI/AAMI ST-72:2011 confirm an endotoxin limit less than 20EU per device.

H. Conclusion:

The Talos® Lumbar (HA) PEEK IBF devices have identical indications for use, intended use, technological characteristics, design, and principles of operation as their predicate devices; as well as similar size and geometric offerings. The differentiating characteristic is the device material, which has been proven to perform equivalently to the predicate device material. The Talos® Lumbar (HA) PEEK IBF devices are substantially equivalent in safety and efficacy to the predicate device.