



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

Meditech Spine, LLC  
Mr. Jason Owens  
Director of Engineering  
1447 Peachtree Street Northeast, Suite 440  
Atlanta, Georgia 30309

October 14, 2015

Re: K150788

Trade/Device Name: Talos® Intervertebral Body Fusion Devices, Talos®-C Cervical  
Intervertebral Body Fusion Devices, Talos®-C(HA) Cervical  
Intervertebral Body Fusion Devices

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: ODP, MAX

Dated: July 15, 2015

Received: July 20, 2015

Dear Mr. Owens:

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" (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

## Indications for Use

510(k) Number (if known)  
K150788

### Device Name

Talos® Intervertebral Body Fusion Devices  
Talos®-C Cervical Intervertebral Body Fusion Devices  
Talos®-C (HA) Cervical Intervertebral Body Fusion Devices

### Indications for Use (Describe)

#### Talos® Intervertebral Body Fusion Devices:

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 autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

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 in the lumbosacral spine. The Talos®-A, Talos®-L, Talos®-P and Talos®-T are intended to be used with supplemental fixation.

#### Talos®-C Cervical Intervertebral Body Fusion Devices:

The Talos®-C Cervical Intervertebral Body Fusion Device is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc (DDD) of the cervical spine at one level from C2-T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by history and radiographic studies. Talos®-C Cervical IBF Devices are intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Non-operative treatment prior to treatment with Talos®-C Cervical Intervertebral Body Fusion Devices is six (6) weeks. Talos®-C Cervical IBF Devices are to be implanted via an open anterior approach. Talos®-C Cervical IBF Devices are also to be used with supplemental fixation.

#### Talos®-C (HA) Cervical Intervertebral Body Fusion Devices:

Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are intervertebral body devices intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level from C2-T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by history and radiographic studies. Talos®-C (HA) Cervical IBF Devices are intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Non-operative treatment prior to treatment with Talos®-C (HA) Cervical Intervertebral Body Fusion Devices is six (6) weeks.

Talos®-C (HA) Cervical IBF Devices are to be implanted via an open anterior approach. Talos®-C (HA) Cervical IBF Devices are also to be used with 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.**

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## 510(k) Summary

As required by section 807.92(c)

Meditech Spine, LLC is requesting marketing clearance for the Indication for Use change to existing Talos® products. Summary prepared on October 9, 2015.

- A. Sponsor/Manufacturer: Meditech Spine, LLC  
Registration Number: 3009405289  
Jason Owens, Operations Manager  
1447 Peachtree St NE Suite 440  
Atlanta, GA 30309  
678-974-5287 Phone  
404-759-2104 Fax
- B. Trade Name: Talos® Intervertebral Body Fusion Devices  
Talos®-C Cervical Intervertebral Body Fusion Devices  
Talos®-C (HA) Cervical Intervertebral Body Fusion Devices  
Common Name: Spinal Implant  
Classification Name: Intervertebral body fusion device (21 CFR 888.3080 Class II, Product Code ODP)  
Intervertebral body fusion device (21 CFR 888.3080 Class II, Product Code MAX)
- C. Predicate Devices: K 142152: Orthofix CONSTRUX Mini PEEK Spacer System, CONSTRUX Mini PEEK Ti Spacer System, Cervical Stand Alone Device (Primary Predicate – Cervical)  
K 143163: Stryker AVS® Spacers and Cages (1<sup>st</sup> Additional – Lumbar)  
K 090707: Meditech Advisors, LLC Talos® Intervertebral Body Fusion Devices  
K 122850: Meditech Advisors, LLC Talos®-C Cervical Intervertebral Body Fusion Devices  
K 142345: Meditech Spine, LLC Talos®-C (HA) Cervical Intervertebral Body Fusion Devices
- D. Device Description:  
The Talos® IBF Device is made of polymer, polyetheretherketone (PEEK). 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.

The Talos®-C Cervical Intervertebral Body Devices (Talos®-C Cervical IBF Devices) are made of the polymer, polyetheretherketone (PEEK). The devices are open devices with ridged teeth on superior and inferior ends to resist implant pullout. The Talos®-C Cervical IBF Devices are rectangular devices and 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, titanium markers at the opposite ends are offered which allows the Talos®-C Cervical IBF Device radiological confirmation for proper positioning.

The Talos®-C (HA) Cervical Intervertebral Body Devices (Talos®-C (HA) Cervical IBF Devices) are made of the polymer, hydroxyapatite impregnated polyetheretherketone (HA PEEK). The devices are open devices with ridged teeth on superior and inferior ends to resist implant pullout. The Talos®-C (HA) Cervical IBF Devices are rectangular devices and 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, titanium markers at the opposite ends are offered which allows the Talos®-C (HA) Cervical IBF Device radiological confirmation for proper positioning.

E. Intended Use:

Talos® Intervertebral Body Fusion Devices:

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 autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

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 in the lumbosacral spine. The Talos®-A, Talos®-L, Talos®-P and Talos®-T are intended to be used with supplemental fixation.

Talos®-C Cervical Intervertebral Body Fusion Devices:

The Talos®-C Cervical Intervertebral Body Fusion Device is an intervertebral body device intended for use in skeletally mature patients with Degenerative Disc (DDD) of the cervical spine at one level from C2-T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by history and radiographic studies. Talos®-C Cervical IBF Devices

are intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Non-operative treatment prior to treatment with Talos®-C Cervical Intervertebral Body Fusion Devices is six (6) weeks.

Talos®-C Cervical IBF Devices are to be implanted via an open anterior approach. Talos®-C Cervical IBF Devices are also to be used with supplemental fixation.

Talos®-C (HA) Cervical Intervertebral Body Fusion Devices:

Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are intervertebral body devices intended for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level from C2-T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by history and radiographic studies. Talos®-C (HA) Cervical IBF Devices are intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Non-operative treatment prior to treatment with Talos®-C (HA) Cervical Intervertebral Body Fusion Devices is six (6) weeks.

Talos®-C (HA) Cervical IBF Devices are to be implanted via an open anterior approach. Talos®-C (HA) Cervical IBF Devices are also to be used with supplemental fixation.

F. Technological Characteristics:

The technological characteristics of the Talos® Intervertebral Body Fusion Devices, Talos®-C Cervical Intervertebral Body Fusion Devices, and Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are identical to the predicate devices in terms of intended use and design. The indications for use are similar. There is a marker material change in the Talos®-C Cervical Intervertebral Body Fusion Devices and in the Talos®-C (HA) Cervical Intervertebral Body Fusion Devices to titanium.

The addition of the allograft comprised of cancellous and/or corticocancellous bone graft to the Talos® Intervertebral Body Fusion Devices, Talos®-C Cervical Intervertebral Body Fusion Devices, and Talos®-C (HA) Cervical Intervertebral Body Fusion Devices does not increase risk. The same risks occur in the subject Talos® Intervertebral Body Fusion Devices, Talos®-C Cervical Intervertebral Body Fusion Devices, and Talos®-C (HA) Cervical Intervertebral Body Fusion Devices as in the predicate devices. Titanium is biocompatible material and commonly used. The cervical predicate is an intervertebral body fusion device that uses titanium markers.

G. Non-clinical Testing:

There have been no design changes made to the Talos® Intervertebral Body Fusion Devices, Talos®-C Cervical Intervertebral Body Fusion Devices, and Talos®-C (HA) Cervical Intervertebral Body Fusion Devices. The purpose of this 510(k) submission is to obtain clearance to use allograft bone comprised of cancellous and/or corticocancellous bone in addition to autologous bone and to change the material of the markers in Talos®-C Cervical Intervertebral Body Fusion Devices and Talos®-C (HA) Cervical Intervertebral Body Fusion Devices. No mechanical testing was performed to determine substantial equivalence.

H. Clinical Testing:

Published retrospective clinical data for lumbar and cervical intervertebral body fusion devices similar to the Talos® Intervertebral Body Fusion Devices, Talos®-C Cervical Intervertebral Body Fusion Devices, and Talos®-C (HA) Cervical Intervertebral Body Fusion Devices is provided in support of this application. The published clinical outcomes demonstrated that the use of allograft in interbody fusion procedures to treat patients with degenerative disc disease as defined above poses no new risks to patients. No design changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.

I. Conclusion:

The Talos® Intervertebral Body Fusion Devices, Talos®-C Cervical Intervertebral Body Fusion Devices, and Talos®-C (HA) Cervical Intervertebral Body Fusion Devices have identical intended use, technological characteristics, design, and principles of operation as their predicate devices; as well as similar indications for use. The proposed devices will have Titanium markers instead of tantalum, which is the same as the predicate device.

There have been no changes to the Talos® Intervertebral Body Fusion Devices, Talos®-C Cervical Intervertebral Body Fusion Devices, and Talos®-C (HA) Cervical Intervertebral Body Fusion Devices since the last 510(k) clearance. The purpose of this 510(k) submission is to obtain clearance to use either autograft and/or allograft bone comprised of cancellous and/or corticocancellous bone graft as a substitute/addition to autologous bone and to change the markers from tantalum to titanium in the cervical implants.