September 11, 2020

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

Re: K201506
Trade/Device Name: Talos®-C Cervical Intervertebral Body Fusion System, Talos®-C (HA) Cervical Intervertebral Body Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: August 12, 2020
Received: August 13, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201506

Device Name

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

Indications for Use *(Describe)*

Talos®-C Cervical Intervertebral Body Fusion Devices

The Talos®-C Cervical Intervertebral Body Fusion Devices are indicated for intervertebral body fusion of the spine in skeletally mature patients. The Talos®-C Cervical Intervertebral Body Fusion Devices are intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The Talos®-C Cervical Intervertebral Body Fusion Devices are intended to be used with supplemental fixation. The Talos®-C Cervical Intervertebral Body Fusion Devices are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. 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 implemented via an open anterior approach approach.

Talos®-C Cervical IBF Devices are also to be used with supplemental fixation. Additionally, the use of Hyperlordotic devices (lordotic angle greater than 7°) are intended to be used exclusively with anterior supplemental fixation.

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

The Talos®-C(HA) Cervical Intervertebral Body Fusion Devices are indicated for intervertebral body fusion of the spine in skeletally mature patients. The Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are intended to be used with supplemental fixation. The Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. 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 implemented via an open anterior approach approach.

Talos®-C (HA) Cervical IBF Devices are also to be used with supplemental fixation. Additionally, the use of Hyperlordotic devices (lordotic angle greater than 7°) 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.

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510(k) Summary

As required by section 807.92(c)

Meditech Spine, LLC is requesting marketing clearance for the Talos®-C and Talos®-C(HA) Cervical Intervertebral Body System

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®-C Cervical Intervertebral Body Fusion System, Talos®-C (HA) Cervical Intervertebral Body Fusion System
Common Name:	Spinal Implant
Classification Name:	Intervertebral Body Fusion Device (21 CFR 888.3080 Class II,Product Code ODP)

C. Predicate Device:

K150788 (Talos®-C and Talos®-C (HA) Devices) (Primary)
K173347 Actilif C FLX (Additional)
K163491 CoRoent Small (Additional)

D. Purpose of Submission:

The Purpose of this submission is to expand product offering of the Talos®-C Cervical Intervertebral Body Devices and the Talos®-C (HA) Cervical Intervertebral Body Devices to include two additional lordotic angles on all footprints greater than 12mm x 12mm (including the introduction of an 18mm x 15mm footprint). Additionally, the revision of the Indication for Use to expand usage from “one level” to “multiple contiguous levels”.

E. Device Description:

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.

F. Indication for Use:

Talos®-C Cervical Intervertebral Body Fusion Devices

The Talos®-C Cervical Intervertebral Body Fusion Devices are indicated for intervertebral body fusion of the spine in skeletally mature patients. The Talos®-C Cervical Intervertebral Body Fusion Devices are intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The Talos®-C Cervical Intervertebral Body Fusion Devices are intended to be used with supplemental fixation. The Talos®-C Cervical Intervertebral Body Fusion Devices are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. 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 implemented via an open anterior approach.

Talos®-C Cervical IBF Devices are also to be used with supplemental fixation. Additionally, the use of Hyperlordotic devices (lordotic angle greater than 7°) are intended to be used exclusively with anterior supplemental fixation.

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

The Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are indicated for intervertebral body fusion of the spine in skeletally mature patients. The Talos®-C (HA) Cervical Intervertebral Body Fusion Devices are intended for use for anterior cervical interbody fusion in patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 - T1. The Talos®-C (HA) Cervical Intervertebral Body Fusion Devices

are intended to be used with supplemental fixation. The Talos-C® (HA) Cervical Intervertebral Body Fusion Devices are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion. 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 implemented via an open anterior approach.

Talos®-C (HA) Cervical IBF Devices are also to be used with supplemental fixation. Additionally, the use of Hyperlordotic devices (lordotic angle greater than 7°) are intended to be used exclusively with anterior supplemental fixation.

G. Technological Characteristics:

The following fundamental technological characteristics of the Talos®-C and Talos®-C (HA) Cervical IBF Devices are identical to the cleared device:

- Intended Use: See IFU
- Material: PEEK / HA PEEK
- Implant Markers: Tantalum / Titanium
- Design: Rectangular, teeth on inferior and superior surfaces, insertion feature
- Sterilization / Packaging: Gamma
- Instrumentation: See Surgical Technique

H. Non-clinical Testing:

Testing according to ASTM F2077-11 and ASTM 2267-04 was performed on the previously cleared Talos®-C and Talos®-C (HA) Cervical IBF Devices. The tests included static compression, compression shear and torsion tests, dynamic compression, compression shear and torsion tests, as well as subsidence testing bending. Finite Element Analysis and engineering analysis were performed on the subject devices to confirm that a new worst-case is not presented in the proposed devices. Talos®-C and Talos®-C (HA) Cervical IBF Devices are superior in mechanical function and properties to the cleared device.

I. Conclusion:

The identical intended use and consistency between the fundamental scientific technology between the Talos®-C and Talos®-C (HA) Cervical IBF Devices allows that both are substantially equivalent to the cleared device.