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

July 1, 2016

Meditech Spine, LLC
Mr. Bruce Dunaway
Chief Design Engineer
1447 Peachtree Street, North East Suite 440
Atlanta, Georgia 30309

Re: K160604
Trade/Device Name: Cure™ Anterior Cervical Plate (ACP) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 16, 2016
Received: May 31, 2016

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 Parts 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

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)*
K160604

Device Name

Cure™ Anterior Cervical Plate (ACP) System

Indications for Use *(Describe)*

Cure™ Anterior Cervical Plate (ACP) System is intended for anterior screw fixation to the C2 to C7 levels of the cervical spine. The system is indicated for use in skeletally mature patients for temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), Spondylolisthesis, Trauma (i.e., fractures or dislocations), Deformity (defined as kyphosis, lordosis, or scoliosis), Pseudarthrosis, and Failed previous fusions.

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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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 Cure™ Anterior Cervical Plate (ACP) 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: Cure™ Anterior Cervical Plate (ACP) System
Common Name: Spinal Implant
Classification Name: Spinal intervertebral body fixation orthosis (21 CFR 888.3060 Class II,Product Code KWQ)

C. Predicate Device: K072650 (IST Anterior Cervical Plate) (Primary)
K926453 (Synthes CSLP) (Additional)

D. Device Description:

Cure™ Anterior Cervical Plate (ACP) System is composed of plates in a wide range of sizes to coincide with the surgical approach and screws that are available in multiple lengths and diameters.

Cure™ Anterior Cervical Plate (ACP) System is manufactured from Grade 23 Titanium (Ti-6Al-4V ELI); manufactured according to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications.

E. Intended Use:

Cure™ Anterior Cervical Plate (ACP) System is intended for anterior screw fixation to the C2 to C7 levels of the cervical spine. The system is indicated for use in skeletally mature patients for temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the Disc confirmed by patient history and radiographic studies), Spondylolisthesis, Trauma (i.e., fractures or dislocations), Deformity (defined as kyphosis, lordosis, or scoliosis), Pseudarthrosis, and Failed previous fusions.

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F. Technological Characteristics:

The technological characteristics of the Cure™ Anterior Cervical Plate (ACP) System is equivalent to the predicate device, except for the central locking mechanism. The central locking mechanism is provided to ensure that the bone screws remain in place.

G. Non-clinical Testing:
Testing according to ASTM F1717 and ASTM F543 was performed on the Cure™ Anterior Cervical Plate (ACP) System to establish equivalency to the predicate device. The tests included static compression bending, static tension, static torsion, dynamic compression bending, screw insertion torque, screw pullout and screw torque to failure.

Cure™ Anterior Cervical Plate (ACP) System is equivalent in mechanical function and properties to the predicate device, establishing equivalency in safety and effectiveness.

H. Conclusion:
The testing completed as well as a comparison of the technological characteristics has demonstrated that the Cure™ Anterior Cervical Plate (ACP) System is substantially equivalent to the predicate device.