May 12, 2020

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

Re: K201136
Trade/Device Name: Cure™ Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 27, 2020
Received: April 28, 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,

Colin O'Neill, M.B.E.
Acting 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)*
K201136

Device Name
Cure™ Lumbar Plate System

Indications for Use *(Describe)*
The Cure™ Lumbar Plate System is intended for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

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 Cure™ OPEL-L (S) Lumbar Plate 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™ Lumbar Plate System
Common Name: Spinal Implant
Classification Name: Spinal intervertebral body fixation orthosis (21 CFR 888.3060 Class II,Product Code KWQ)

C. Predicate Device: K171538 (Cure™ Lumbar Plate System)

D. Device Description:

The Cure™ Lumbar Plate (Cure™ OPEL-L (S)) is available in a range of sizes to coincide with the surgical approach. The Cure™ OPEL-L (S) is similar to the Cure™ Anterior Lumbar plate with the exceptions of replacing the graft window with a through hole, the inclusion of a central rib at the through hole location and convexity in the sagittal plane at the screw hole locations.

All Cure™ Lumbar Plates continue to be 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. Indications for Use:

The Cure™ Lumbar Plate System is intended for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine

instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

F. Technological Characteristics:

The fundamental technological characteristics of the Cure™ OPEL-L (S) is identical to the predicate device.

G. Non-clinical Testing:

An engineering analysis was performed on the Cure™ OPEL-L (S) to demonstrate equivalency to the previously tested predicate device (Cure™ Anterior Lumbar Plate System) with respect to static compression bending, static tension, and dynamic compression bending per ASTM F1717.

Cure™ OPEL-L (S) Lumbar Plates are superior in mechanical function and properties to the predicate device.

H. Conclusion:

The identical intended use and consistency between the fundamental scientific technology between the Cure™ OPEL-L (S) Lumbar Plate allows that it is substantially equivalent to the predicate device.