



Curiteva, Inc.
Eric Linder
Chief Technology Officer
25127 Will McComb Drive
Suite 100
Tanner, Alabama 35671

February 29, 2024

Re: K233360

Trade/Device Name: Curiteva Thoracolumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 29, 2023
Received: September 29, 2023

Dear Eric Linder:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

**Eileen
Cadel -S**

Digitally signed
by Eileen Cadel -
S
Date: 2024.02.29
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for

Colin O'Neill, M.B.E.

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

Indications for Use

510(k) Number (if known)

K233360

Device Name

Curiteva Thoracolumbar Plate System

Indications for Use (Describe)

The Curiteva Thoracolumbar Plate System Two Hole and Four Hole Plates are 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 in skeletally mature patients 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.

The Curiteva Thoracolumbar Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

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

A. Submitter Information

Submitter: Curiteva, Inc.
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Phone: (256) 213-1057
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Contact Person: Eric Linder
regulatory@curiteva.com

Date Prepared: February 29, 2024

B. Device Information

Trade Name: Curiteva Thoracolumbar Plate System

Common Name: Spinal Fixation System

Classification Name: Spinal Intervertebral Body Fixation Orthosis

Device Classification: Class II (per 21 CFR 888.3060)

Product Code: KWQ

Predicate Device(s): Primary: Meditech Spine Cure Lumbar Plate System (K171538 / K180090)
Additional: Stryker LITe Plate System (K142699)
Additional: Genesys Spine Binary Lumbar Plate System (K173885)
Additional: Innovasis Kestrel Buttress Plate System (K181063)

C. Device Description

The Curiteva Thoracolumbar Plate System is an internal fixation device for spinal surgery that consists of various configurations of spinal plates and bone screws. The implant configurations are available in different types and sizes so that adaptations can be made to take into account pathology and individual patient anatomy. The plates come preformed with holes to receive bone screws. Screws are used to attach the plates to bone. All system implants are manufactured from Titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

D. Indications for Use

The Curiteva Thoracolumbar Plate System Two Hole and Four Hole Plates are 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 in skeletally mature patients 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.

The Curiteva Thoracolumbar Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

E. Technological Characteristics

As was established in this submission, the subject Curiteva Thoracolumbar Plate System is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and to have similar technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

F. Performance Data

Non-clinical testing performed on the Curiteva Thoracolumbar Plate System supports substantial equivalence to predicate devices. The following testing was performed:

- Static compression bending per ASTM F1717
- Dynamic compression bending per ASTM F1717
- Static torsion per ASATM F1717
- Static cantilever bending per ASTM F2193
- Dynamic cantilever bending per ASTM F2193

The results of non-clinical testing demonstrate that the strength and performance of the Curiteva Thoracolumbar Plate System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

G. Conclusion

Based on the indications for use, technological characteristics, non-clinical performance testing, and comparison to predicate devices, the subject Curiteva Thoracolumbar Plate System has been shown to be substantially equivalent to legally marketed predicate devices.