



August 2, 2018

Curiteva, LLC  
Mr. Eric Linder  
Chief Operating Officer  
25127 Will McComb Drive, Suite 100  
Tanner, Alabama 35671

Re: K181562

Trade/Device Name: Curiteva Anterior Cervical Plate System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: Class II  
Product Code: KWQ  
Dated: June 13, 2018  
Received: June 14, 2018

Dear Mr. 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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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)

K181562

Device Name

Curiteva Anterior Cervical Plate System

### Indications for Use (Describe)

The Curiteva Anterior Cervical Plate System is intended for anterior fixation of the cervical spine (C2-T1) as an adjunct to fusion. The system is intended to provide temporary stabilization during the development of cervical spinal fusion in patients with the following: degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformity (e.g., kyphosis, lordosis, scoliosis), tumors, pseudarthrosis, and/or failed previous fusion.

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, LLC  
25127 Will McComb Drive, Suite 100  
Tanner, AL 35671  
Phone: (256) 213-1057  
Fax: (256) 213-1058

Contact Person: Eric Linder  
[regulatory@curiteva.com](mailto:regulatory@curiteva.com)

Date Prepared: August 2, 2018

### B. Device Information

Trade Name: Curiteva Anterior Cervical Plate System  
Common Name: Anterior Cervical Plate System  
Classification Name: Appliance, Fixation, Spinal Intervertebral Body  
Device Classification: Class II (per 21 CFR 888.3060)  
Product Code: KWQ  
Classification Panel: Division of Orthopedic Devices  
Predicate Device(s): Primary: Synthes Anterior CSLP System – K030866  
Additional: DeGen Medical Hyper-C Anterior Cervical Plate System -- K150759

### C. Device Description

The Curiteva Anterior Cervical Plate System consists of screws and plates. These implants are available in different sizes so that adaptations can be made to take into account pathology and individual patient anatomy. All implants are manufactured from Titanium alloy (Ti-6Al-4V) that conforms to ASTM F136.

### D. Indications for Use

The Curiteva Anterior Cervical Plate System is intended for anterior fixation of the cervical spine (C2-T1) as an adjunct to fusion. The system is intended to provide temporary stabilization during the development of cervical spinal fusion in patients with the following: degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient

history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformity (e.g., kyphosis, lordosis, scoliosis), tumors, pseudarthrosis, and/or failed previous fusion.

#### **E. Technological Characteristics**

As was established in this submission, the subject Curiteva Anterior Cervical 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 the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.

#### **F. Performance Data**

The Curiteva Anterior Cervical Plate System was mechanically tested in the following test modes: static and dynamic compression bend per ASTM F1717, static torsion per ASTM F1717, and axial screw pushout.

The results of this non-clinical testing show that the strength and performance of the Curiteva Anterior Cervical 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, performance testing, and comparison to predicate devices, the subject Curiteva Anterior Cervical Plate System has been shown to be substantially equivalent to legally marketed predicate devices.