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

July 9, 2018

Re: K181261
Trade/Device Name: Curiteva Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: May 9, 2018
Received: May 11, 2018

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 (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 Part 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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181261

Device Name
Curiteva Cervical Interbody Fusion System

Indications for Use *(Describe)*

The Curiteva Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2 – T1 inclusive). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. Implants are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) and supplemental spinal fixation systems that have been cleared for use in the cervical spine. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with the device.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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
Date Prepared:	May 9, 2018

B. Device Information

Trade Name:	Curiteva Cervical Interbody Fusion System
Common Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Fusion Device With Bone Graft, Cervical
Device Classification:	Class II (per 21 CFR 888.3080)
Product Code:	ODP
Classification Panel:	Division of Orthopedic Devices
Predicate Device(s):	Primary: Globus Medical PATRIOT Cervical Spacers, (including COLONIAL and COLONIAL TPS) -- K143578 Additional: DeGen Medical Latitude-C Cervical Interbody Spacer System -- K151496 Additional: Titan Spine Endoskeleton TC -- K100889

C. Device Description

The Curiteva Cervical Interbody Fusion System implants are available in a variety of different footprints, styles and sizes to accommodate the individual pathology and anatomical conditions of the patient. The implants are generally box-shaped with an open central chamber to permit packing with bone graft to facilitate fusion. The superior and inferior surfaces of the construct have a pattern of teeth to provide increased stability and to help prevent movement of the device.

The Curiteva Cervical Interbody Fusion System implants are manufactured from PEEK (per ASTM F2026) with Tantalum markers (per ASTM F560), or Titanium alloy (Ti-6Al-4V) that conforms to

ASTM F136. The PEEK implants are available with or without a medical grade commercially pure titanium (CpTi) plasma coating (per ASTM F1580) on the superior and inferior surfaces.

D. Indications for Use

The Curiteva Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2 – T1 inclusive). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. Implants are intended to be used with autograft and/or allograft bone (comprised of cancellous and/or corticocancellous bone graft) and supplemental spinal fixation systems that have been cleared for use in the cervical spine. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with the device.

E. Technological Characteristics

As was established in this submission, the subject Curiteva Cervical Interbody Fusion 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 Cervical Interbody Fusion System was mechanically tested in the following test modes: static and dynamic compression per ASTM F2077, static and dynamic torsion per ASTM F2077, subsidence per ASTM F2267, expulsion, and wear debris characterization per ASTM F1877.

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