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

September 9, 2021

Re: K210402
Trade/Device Name: Curiteva Sacroiliac Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: July 30, 2021
Received: August 2, 2021

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. 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210402

Device Name
Curiteva Sacroiliac Joint Fusion System

Indications for Use *(Describe)*
The Curiteva Sacroiliac Joint Fusion System is intended for sacroiliac (SI) joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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, Inc.
25127 Will McComb Drive
Tanner, AL 35671
Phone: (256) 213-1057
Fax: (256) 213-1058

Contact Person: Eric Linder
regulatory@curiteva.com

Date Prepared: July 30, 2021

B. Device Information

Trade Name:	Curiteva Sacroiliac Joint Fusion System
Common Name:	Sacroiliac Joint Fixation / Sacroiliac Joint Fusion System
Classification Name:	Smooth or threaded metallic bone fixation fastener
Device Classification:	Class II (per 21 CFR 888.3040)
Product Code(s):	OUR
Classification Panel:	Orthopedic
Predicate Device(s):	Primary: SI-Technology SI-DESIS Screws – K151462 Additional: Genesys Spine Sacroiliac Joint Fusion System – K191748 Additional: Synthes 6.5mm Cannulated Screw – K021932

C. Device Description

The Curiteva Sacroiliac Joint Fusion System consists of screws in various diameters, lengths and thread configurations to accommodate variations in patient anatomy. The screws are designed to be implanted across the sacroiliac joint to stabilize and aid in the fusion of the sacroiliac joint. Optional washers are included to aid in the distribution of load across the bone surface directly apposing the screw head.

The Curiteva Sacroiliac Joint Fusion System implants are manufactured from medical-grade titanium alloy in accordance with ASTM F136. All system implants are intended for single use only and should not be reused under any circumstances.

D. Indications for Use

The Curiteva Sacroiliac Joint Fusion System is intended for sacroiliac (SI) joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

E. Technological Characteristics

As was established in this submission, the subject Curiteva Sacroiliac Joint 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 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

The Curiteva Sacroiliac Joint Fusion System was mechanically tested in the following test modes:

- Static four-point bending per ASTM F2193
- Dynamic four-point bending per ASTM F2193
- Static torsion per ASTM F543
- Static axial pullout per ASTM F543

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