January 6, 2023

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

Re: K223200
Trade/Device Name: Curiteva Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 30, 2022
Received: October 13, 2022

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K223200

Device Name
Curiteva Navigation System

Indications for Use *(Describe)*
The Curiteva Navigation System is intended to be used during the preparation and placement of Curiteva screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Curiteva Navigation System is specifically designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

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 – K223200

Submitter's Name:	Curiteva, Inc.
Submitter's Address:	25127 Will McComb Dr. Tanner, Alabama 35671
Submitter's Telephone:	(256) 213-1057
Contact Person:	Eric Linder regulatory@curiteva.com
Date Summary was Prepared:	January 5, 2023
Trade or Proprietary Name:	Curiteva Navigation System
Common or Usual Name:	Orthopedic Stereotaxic Instrument
Classification:	Class II per 21 CFR §882.4620
Product Code:	OLO
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Curiteva Navigation System instruments are reusable surgical instruments for use with the Medtronic® StealthStation® Navigation System S7 v2.1.0 and S8 v1.2.0 (1.2.0-20) to assist surgeons in precisely locating anatomical structures in open or minimally invasive procedures for preparation and placement of Curiteva screws.

The Curiteva Navigation System includes awls, probes, taps, drills, and drivers. The Curiteva Navigation System instruments are to be used with the Curiteva Pedicle Screw System or the Curiteva Sacroiliac Joint Fusion System, as specified.

All instruments are made of stainless steel per ASTM F899. The Curiteva Navigation System instruments are not compatible with implants from other manufacturers and are designed for use only with Medtronic StealthStation Navigation System hardware and software.

INDICATIONS FOR USE

The Curiteva Navigation System is intended to be used during the preparation and placement of Curiteva screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Curiteva Navigation System is specifically designed for use with the Medtronic StealthStation® System, which is indicated for

any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are similar between the subject, predicate, and reference devices:

- Indications for use
- Materials of manufacture
- Principles of operation
- Design

Table 1 - Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code
K161210 (PRIMARY) / K143628 / K143375 / K140454	Medtronic Navigated Instruments	Medtronic Sofamore Danek USA, Inc.	OLO

Table 2 - Reference Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code
K191810	Curiteva Pedicle Screw System	Curiteva, Inc.	NKB, KWP
K210402	Curiteva Sacroiliac Joint Fusion System	Curiteva, Inc.	OUR

PERFORMANCE DATA

The Curiteva Navigation System instruments have been tested per ASTM F2554-18, “Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems”. Dimensional comparisons were also made between the subject and predicate devices.

The results of this non-clinical testing show that the performance of the Curiteva Navigation System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Curiteva Navigation System is substantially equivalent to the predicate device.