February 3, 2026

Ulrich Medical USA, Inc.
% Hannah Taggart
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K252087
Trade/Device Name: Navigation Module of the Cortium® System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 6, 2026
Received: January 6, 2026

Dear Hannah Taggart:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K252087

Device Name
Navigation Module of the Cortium® System

Indications for Use *(Describe)*
The Navigation Module of the Cortium® System is intended to be used during the preparation and placement of Cortium® Universal OCT Spinal Fixation System screws during spinal surgery, to assist the surgeon in precisely locating anatomical structures. The Navigation Module of the Cortium® System is 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 a vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks for the anatomy. Instruments of the Navigation Module of the Cortium® System are not intended for navigation of occipital screws.

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

# K252087 510(K) SUMMARY

| | |
|---|---|
| Submitter's Name: | ulrich Medical USA Inc. |
| Submitter's Address: | 3700 East Plano Parkway, Suite 200<br>Plano TX 75074 |
| Submitter's Telephone: | 469-238-0800 |
| Contact Person: | Hannah Taggart, MS, RAC<br>ATS Colorado Springs<br>1-719-457-1152 |
| Date Summary was Prepared: | January 21, 2026 |
| Trade or Proprietary Name: | Navigation Module of the Cortium® System |
| Device Classification Name: | Orthopedic Stereotaxic Instrument |
| Common Name: | Navigated Instruments |
| Classification & Regulation #: | Class II per 21 CFR 882.4560 |
| Product Code: | OLO |
| Classification Panel: | Restorative, Repair, and Trauma Devices (DHT6C) |

## DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Navigation Module of the Cortium® System contains non-sterile, reusable, manual surgical instruments including drills, taps, and screwdrivers. The instruments are manufactured from stainless steels which conform to ASTM F899. The instruments are designed for use with the Medtronic StealthStation surgical navigation system for implantation of the Cortium® Universal OCT Spinal Fixation System components. Instruments of the Navigation Module of the Cortium® System were tested for compatibility using StealthStation S8 software version 2.1.0.

Instruments of the Navigation Module of the Cortium® System are not intended for navigation of occipital screws.

## INDICATIONS FOR USE

The Navigation Module of the Cortium® System is intended to be used during the preparation and placement of Cortium® Universal OCT Spinal Fixation System screws during spinal surgery, to assist the surgeon in precisely locating anatomical structures. The Navigation Module of the Cortium® System is 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 a vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks for the anatomy. Instruments of the Navigation Module of the Cortium® System are not intended for navigation of occipital screws.

## 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 and predicates:

- Principles of Operation
- Indications for Use
- Materials
- Style of Instruments
- Sizes

- Compatible Screw Options
- Instrument Critical Geometries and Functional Length

**Predicate Devices**

| 510k Number | Trade or Proprietary or Model Name | Manufacturer | Product Code | Predicate Type |
|---|---|---|---|---|
| K143628 | Medtronic Navigated VERTEX SELECT® Instruments | Medtronic | OLO | Primary |
| K170679 | Medtronic Navigation Instruments | Medtronic | OLO | Additional |
| K230614 | Cortium® Universal OCT Spinal Fixation System | ulrich Medical USA, Inc. | NKB | Reference |
| K200845 | Navigation Module of the Momentum System | ulrich Medical USA, Inc. | OLO | Reference |

## PERFORMANCE DATA

The Navigation Module of the Cortium® System has been assessed in a critical geometry assessment and software registration verification. The results of this non-clinical testing show that the Navigation Module of the Cortium® System is substantially equivalent in positional accuracy to legally marketed predicate devices.

The subject devices are identical in manufacturing materials and processes to previously cleared instruments (K230614) with the same contact type and duration, demonstrating biocompatibility of patient-contacting materials. Cleaning and sterilization methods are the same as those used for instrument systems cleared in K200845 and K230614, respectively, and were previously validated.

## CONCLUSION

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