September 10, 2020

Ulrich Medical USA
Hans Stover
President & CEO
18221 Edison Avenue
Chesterfield, Missouri 63005

Re: K200845
Trade/Device Name: Navigation Module of the Momentum System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 30, 2020
Received: August 13, 2020

Dear Hans Stover:

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

510(k) Number *(if known)*

K200845

Device Name
Navigation Module of the Momentum System

Indications for Use *(Describe)*

The Navigation Module of the Momentum System is intended to be used during the preparation and placement of Momentum Posterior Spinal Fixation System screws during spinal surgery, to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Navigation Module of the Momentum System is designed for use with the Medtronic SteathStation 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.

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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K200845

510(k) Summary

Date:	30 March 2020
Sponsor:	ulrich medical USA, Inc. 18221 Edison Avenue Chesterfield, MO 63005 (636) 519-0268 Office (636) 519-0271 Fax
Sponsor Contact:	Hans Stover, President & CEO
Proposed Trade Name:	Navigation Module of the Momentum System
Common Name:	Orthopaedic navigation system
Regulatory Class:	Class II
Regulation Number:	21 CFR 882.4560
Regulation Name:	Stereotaxic Instrument
Product Code:	OLO
Device Description:	The Navigation Module of the Momentum System contains non-sterile, reusable manual instruments including taps and screwdrivers. The instruments are designed for use with the Medtronic StealthStation System for implantation of the Momentum Posterior Spinal Fixation System components.
Indications for Use:	The Navigation Module of the Momentum System is intended to be used during the preparation and placement of Momentum Posterior Spinal Fixation System screws during spinal surgery, to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Navigation Module of the Momentum System is designed for use with the Medtronic SteathStation 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.
Materials:	The Navigation Module instruments are manufactured from stainless steels per ASTM F899.
Primary Predicate:	Navigated CD Horizon® Solera® Screwdrivers and Taps (Medtronic Sofamor Danek, USA Inc. – K140454)
Additional Predicates:	Navigated CD Horizon® Solera™ Screwdrivers, CD Horizon® Solera™ Taps and CD Horizon® Legacy™ Taps (Medtronic Navigation, Inc. – K124004)
Performance Data:	Navigation accuracy, registration, rigidity and simulated surgery validations were performed in side-by-side testing of the Navigation Module of the Momentum System and predicate devices. The test results demonstrate that the Navigation Module of the Momentum System performance is substantially equivalent to the predicate devices.
Technological Characteristics:	The Navigation Module of the Momentum System possesses similar technological characteristics as one or more of the predicate devices. The fundamental scientific technology of the Navigation Module of the Momentum System is the same as previously cleared devices.

Conclusion: The Navigation Module of the Momentum System possesses the same intended use and similar technological characteristics as the predicate devices. The Navigation Module of the Momentum System is substantially equivalent for its intended use.