June 26, 2020

Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc.
Kurtis Hunsberger
Principal Regulatory Affairs Specialist
375 River Park Circle
Marquette, Michigan 49855

Re: K200095
Trade/Device Name: Streamline Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 19, 2020
Received: June 22, 2020

Dear Kurtis Hunsberger:

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)*
K200095

Device Name
Streamline Navigated Instruments

Indications for Use *(Describe)*
Streamline Navigated Instruments are intended to be used during the preparation and placement of screws from the Streamline TL and MIS Systems and preparation of screws from the Streamline OCT System during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are 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

K200095 Streamline Navigated Instruments

As required by 21 CFR 807.92

Date Prepared:	June 25, 2020
Submitter:	Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc. 375 River Park Circle Marquette, MI 49855 USA Phone: (906) 226-9909 Fax: (906) 225-5868
Contact Information:	Kurtis Hunsberger Principal Regulatory Affairs Specialist RTI Surgical, Inc. khunsberger@rtix.com 952-698-9931
Name of Device:	Streamline® Navigated Instruments
Common Name:	Orthopedic Stereotaxic Instrument
Classification Name:	Stereotaxic Instrument
Regulation Number:	21 CFR 882.4560
Regulatory Class:	Class II
Product Code:	OLO
Panel:	Orthopedic Device Panel, Panel Code 84
Predicate Device:	Primary Predicate: K140454 Medtronic Navigated Instruments Reference Predicate: K173338 Medtronic Navigated Instruments (Navigated INFINITY™ Instruments)
Device Description:	The Streamline Navigated Instruments are non-sterile, reusable instruments for use with the Medtronic StealthStation Navigation System to assist surgeons in precisely locating anatomical structures in either open or minimally invasive (MIS) procedures for preparation and placement of screws from the Streamline TL Spinal Fixation System and Streamline MIS Spinal Fixation System and preparation of screws from the Streamline OCT Occipito-Cervico-Thoracic System.

	The Streamline Navigated Instruments include pedicle finders, modular handle, taps, drills, and screw inserters designed for use with Streamline TL, Streamline MIS, and Streamline OCT Systems. The instruments are manufactured from stainless steel (ASTM F899).
Indications for Use:	Streamline Navigated Instruments are intended to be used during the preparation and placement of screws from the Streamline TL and MIS Systems and preparation of screws from the Streamline OCT System during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are 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.
Comparison of Technological Characteristics with the Predicate Device:	Both the subject and predicate devices are stereotactic instruments designed for use with optical navigation. At a high level, the subject and predicate devices are based on the following same technological elements. The subject and predicate devices: • Are used with the Medtronic StealthStation Navigation System • Are used during preparation and placement of screws during spinal surgery • Include the same instrument types (probes, drills, taps, drivers, modular handles) • Incorporate a NavLock collar feature designed for connection to the NavLock tracker for use with navigation • Have the same/similar critical dimensions of critical length from NavLock tracker to distal tip of instruments • Are used with pedicle screws of same diameters and lengths • Have accuracy testing performed per ASTM F2554 • Are constructed from ASTM F899 stainless steel • Are reusable and provided non-sterile • Are designed for use with their respective spinal fixation systems There are no technological differences between the subject and predicate devices. However, there are minor dimensional differences inherent to the instruments in the respective spinal fixation systems such as instrument/implant interface features and tap threading. These minor dimensional differences do not affect the critical dimensions of the instrument and do not affect performance with navigation.
Performance Data:	Streamline Navigated Instruments have been tested per ASTM F2554-18 “Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems.” Dimensional comparison and tolerance analysis of the Streamline Navigated Instruments to the predicate Medtronic Navigated Instruments was conducted to ensure the Streamline Navigated Instruments are acceptable for their

	intended use, ensure functionality and compatibility with the Medtronic StealthStation® System. The results of this non-clinical testing show that performance of the Streamline Navigated Instruments is sufficient for their intended use and demonstrate substantial equivalence to legally marketed predicate devices.
Conclusion:	The supporting evidence in this submission concludes the subject Streamline Navigated Instruments are substantially equivalent to the predicate devices.