DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 22, 2016

Pioneer Surgical Technology, Incorporated (DBA RTI Surgical, Incorporated)
Ms. Sarah Pleaugh
Regulatory Affairs Specialist
375 River Park Circle
Marquette, Michigan 49855

Re: K161498
Trade/Device Name: Streamline OCT Occipito-Cervico-Thoracic System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: May 31, 2016
Received: June 1, 2016

Dear Ms. Pleaugh:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161498

Device Name
Streamline OCT Occipito-Cervico-Thoracic System

Indications for Use *(Describe)*

The Streamline OCT Occipito-Cervico-Thoracic System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion when using autograft and/or allograft for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 to T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Streamline OCT System may be connected to the Quantum Spinal Fixation System, Streamline MIS Spinal Fixation System or Streamline TL Spinal System using connectors and/or transition rods.

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.

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510(k) Summary
As required by 21 CFR 807.92

Prepared: August 17, 2016

Company:	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:	Sarah Pleaugh, Regulatory Affairs Specialist
Trade name:	Streamline OCT Occipito-Cervico-Thoracic System
Device name:	Streamline OCT Occipito-Cervico-Thoracic System
Classification:	Unclassified; Pre-amendment device (Product Code NKG, KWP)
Panel:	Panel Code 87
Primary Predicate:	Medtronic VERTEX Reconstruction System (K143471)
Additional Predicates:	Streamline OCT Spinal System (K150254) DePuy Mountaineer OCT Spinal System (K151885)
Description:	The Streamline OCT System consists of a variety of rods, hooks, polyaxial screws, high-angle screws, locking caps, occipital plates, occipital screws, and connecting components used to build an occipito-cervico-thoracic spinal construct. System components are manufactured from ASTM F136 medical grade titanium alloy and ASTM F1537 medical grade cobalt chromium molybdenum alloy. Medical grade titanium alloy and medical grade cobalt chromium molybdenum alloy may be used together. The system should be implanted using only the surgical instruments designed for the system. The purpose of this submission is to: expand the use of the system to include the use of screws in the posterior cervical spine, add line extension components and modify an existing component.
Indications for Use:	The Streamline OCT Occipito-Cervico-Thoracic System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion when using autograft and/or allograft for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 to T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The system is also intended to restore the integrity of the spinal column

	even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the Streamline OCT System may be connected to the Quantum Spinal Fixation System, Streamline MIS Spinal Fixation System or Streamline TL Spinal System using connectors and/or transition rods.
Summary of Technological Characteristics:	The subject system has a similar fundamental scientific technology as the predicate K143471 Medtronic VERTEX Reconstruction System (primary predicate) and reference devices. The subject system utilizes equivalent surgical approaches, fundamental technology, designs, materials, sterilization and packaging as the predicate devices.
Discussion of Supporting Clinical Evidence and Non-Clinical Testing:	Engineering analysis was presented to confirm that the subject components do not introduce new worst-case components or impact previously completed construct testing. For device modifications, re-creation testing was completed to demonstrate the modifications improve performance. In support of the indications for use change, published literature and previously completed mechanical testing (ASTM F1717 and ASTM F2706) demonstrate that the subject and predicate systems are substantially equivalent. No new risks to safety or effectiveness were raised by the published literature search or non-clinical testing.
Substantial Equivalence and Comparison to Legally Marketed Devices:	The subject system is substantially equivalent to the K143471 Medtronic VERTEX Reconstruction System (primary predicate) and K151885 DePuy Mountaineer OCT Spinal System (reference device). With respect to the implants used to create the constructs utilized for the indications sought, the subject devices are the same or similar in design to the Streamline OCT devices most recently cleared in K150254 (earlier clearances of the system are noted in this submission for reference purposes). The design features, materials, indications for use, surgical approach, and fundamental technology are substantially equivalent to predicate devices. Previously completed mechanical testing and the clinical evidence provided in this submission demonstrate there are no new risks to safety or efficacy raised by the subject Streamline OCT System.