



Food and Drug Administration
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Pioneer Surgical Technology, Inc. (DBA RTI Surgical, Inc.)
Ms. Sarah Pleaugh
Regulatory Affairs Specialist
375 River Park Circle
Marquette, Michigan 49855

August 18, 2017

Re: K172139

Trade/Device Name: Streamline OCT Occipito-Cervico-Thoracic System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: July 13, 2017
Received: July 17, 2017

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 Part 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 (DICE) 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 (DICE) 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172139

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 of 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**

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 Prepared: July 13, 2016
Contact: Trade name:	Sarah Pleaugh, Regulatory Affairs Specialist Streamline OCT Occipito-Cervico-Thoracic System
Common name:	Posterior Occipito-Cervico-Thoracic System
Classification:	Unclassified; Pre-amendment device (Product Code NKG - Orthosis, Cervical Pedicle Screw Spinal Fixation) Class II; 21 CFR 888.3050 (Product Code KWP - Appliance, Fixation, Spinal Interlaminar)
Panel:	Panel Code 87
Predicates:	Primary Predicate: Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc. Streamline OCT System (K161498) Additional Predicates: Medtronic VERTEX Reconstruction System (K143471) DePuy Summit/Mountaineer OCT System (K151885) Exactech Gibralt® Spine System and Gibralt® Occipital Spine System (K160697)
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. Cases and caddies are supplied for sterilization and transport of the implants and instruments. The purpose of this submission is to modify and add components to the system.
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

	<p>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.</p> <p>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.</p> <p>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.</p>
<p>Summary of Technological Characteristics:</p>	<p>The subject system has a similar fundamental scientific technology as the predicates. The subject system utilizes equivalent surgical approaches, fundamental technology, designs, materials, sterilization and packaging as the predicate devices.</p>
<p>Discussion of Supporting Clinical Evidence and Non-Clinical Testing:</p>	<p>Engineering analysis, including ASTM F1798 testing, was presented to confirm that the subject components do not introduce new worst-case components or cause the system to be more susceptible to loosening or failure. Mechanical construct testing (ASTM F1717 and ASTM F2706) demonstrated that the subject and predicate systems are substantially equivalent. No new risks to safety or effectiveness were raised by the non-clinical testing.</p>
<p>Substantial Equivalence and Comparison to Legally Marketed Devices:</p>	<p>The design features, materials, indications for use, surgical approach, mechanical performance and fundamental technology are substantially equivalent to predicate devices. This submission demonstrates there are no new risks to safety or efficacy raised by the subject Streamline OCT System.</p>