DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 28, 2015

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

Re: K150254
Trade/Device Name: Streamline OCT Occipito-Cervico-Thoracic System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: February 2, 2015
Received: February 3, 2015

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 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 yours,

Lori A. Wiggins -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)*

K150254

Device Name
Streamline OCT Occipito-Cervico-Thoracic System

Indications for Use *(Describe)*

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Streamline OCT Occipito-Cervico-Thoracic System is intended for: degenerative disc disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture/ dislocation, atlanto/axial fracture with instability, occipito-cervical dislocation, deformities or curvature, tumors, pseudoarthrosis, and revision of previous cervical and upper thoracic spine surgery.

The occipital bone screws are limited to occipital fixation only. The use of the pedicle screws (standard and high angle) is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The pedicle screws are not intended for use in the cervical spine.

The hooks, connectors, and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/ upper thoracic (C1-T3) spine.

The Streamline OCT System can also be linked to FDA cleared pedicle screw systems (e.g., Quantum Spinal Fixation System, Streamline MIS Spinal Fixation System or Streamline TL Spinal System) using connectors.

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
K15 0254

Sponsor:	Pioneer Surgical Technology, Inc. (DBA RTI Surgical, Inc.) 375 River Park Circle Marquette, MI 49855 USA Contact: Sarah Pleaugh Phone: (906) 225-5861 Fax: (906) 226-4459 Prepared: February 2, 2015
Trade name: Common name:	Streamline OCT Occipito-Cervico-Thoracic System Posterior Occipito-Cervico-Thoracic System
Classification:	Class II per §888.3050 Spinal Interlaminal Fixation Orthosis
Product Codes/ Panel:	KWP Panel Code 87
Predicates:	K133374 Pioneer Streamline OCT Occipito-Cervico-Thoracic System K132332 DePuy Mountaineer OCT Spinal System K133556 Zimmer Virage OCT Spinal System
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. The purpose of this submission is to add components to the predicate K133374 Streamline OCT System.
Materials:	The Streamline OCT System components are manufactured from ASTM F136 medical grade titanium alloy and ASTM F1537 medical grade cobalt chromium. Medical grade titanium alloy and medical grade cobalt chromium may be used together.
Technological Characteristics:	The subject components are overall similar in technological characteristics as compared to the predicates in terms of: - Basic technology: polyaxial screws with threaded locking mechanism, pre-bent OCT spinal rods - Materials: Titanium alloy and cobalt chromium alloy - Design: sizes and dimensions equivalent or comparable to predicates There are no significant differences between the subject and predicate devices which would raise new issues of safety or effectiveness. Page 1 of 2

Intended Use:	When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Streamline OCT Occipito-Cervico-Thoracic System is intended for: degenerative disc disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture/ dislocation, atlanto/axial fracture with instability, occipito-cervical dislocation, deformities or curvature, tumors, pseudoarthrosis, and revision of previous cervical and upper thoracic spine surgery. The occipital bone screws are limited to occipital fixation only. The use of the pedicle screws (standard and high angle) is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The pedicle screws are not intended for use in the cervical spine. The hooks, connectors, and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/ upper thoracic (C1-T3) spine. The Streamline OCT System can also be linked to FDA cleared pedicle screw systems (e.g., Quantum Spinal Fixation System, Streamline MIS Spinal Fixation System or Streamline TL Spinal System) using connectors.
Non-Clinical Performance Data:	Engineering analysis was sufficient to demonstrate that the subject components do not introduce new worst-case components. Previously completed Streamline OCT System testing is sufficient to support the performance of the subject product and therefore, no new testing was required for the determination of substantial equivalence. The subject product is expected to be as safe, as effective, and perform as well as the predicate.
Substantial Equivalence:	The subject system is substantially equivalent to previously cleared posterior OCT systems based on comparison of intended use, materials, design, technological characteristics, and performance.