January 14, 2020

Pioneer Surgical Technology, Inc. (DBA RTI Surgical, Inc.)
% Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

Re: K192800
Trade/Device Name: Streamline TL Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: December 13, 2019
Received: December 13, 2019

Dear Justin Eggleton:

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,

for

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal 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)*
K192800

Device Name
Streamline TL Spinal Fixation System

Indications for Use *(Describe)*
The Streamline TL Spinal Fixation System components are non-cervical spinal fixation devices intended as an adjunct to fusion for use as a pedicle screw (T1-S2), posterior hook (T1-L5) or sacral/iliac screw fixation. Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudarthrosis, and failed previous fusion.

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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1. 510(k) Summary

Name: Streamline TL Spinal System

Device Trade Name: Streamline TL Spinal Fixation System

Common Name: Pedicle screw system

Manufacturer: Pioneer Surgical Technology, Inc. DBA, RTI Surgical, Inc.
375 River Park Circle
Marquette, MI 49855 USA
Registration no: 1833824

Contact: Mr. Kurtis Hunsberger
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Minnetonka, MN 55343 USA

Prepared by: Mr. Justin Eggleton
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Date Prepared: September 30th, 2019

Classifications: 21 CFR §888.3070, Thoracolumbosacral Pedicle Screw System

Class: II

Product Codes: NKB, KWP

Panel: Orthopaedic and Rehabilitation Devices Panel; Panel Code 87

Indications for Use:
The Streamline TL Spinal Fixation System components are non-cervical spinal fixation devices intended as an adjunct to fusion for use as a pedicle screw (T1-S2), posterior hook (T1-L5) or sacral/iliac screw fixation. Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudarthrosis, and failed previous fusion.

Device Description:
The Streamline TL Spinal System consists of a variety of rods, screws (poly-axial, fixed, and reduction), rod connectors, crosslinks, set screws, hooks and other connecting components used to build a spinal construct. The implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The Streamline TL Spinal System includes Class I manual instrumentation to facilitate implantation of the device components.

Reason for Submission (Modifications to Predicate)
The purpose of this premarket submission is to modify the implants to include hook implants as from a predicate system and add cortical-cancellous bone screws. Additionally, this premarket submission discloses instrument modifications including a pistol rod reducer. Finally, this submission includes an update to the labeling of the Streamline TL Spinal System to acknowledge its Magnetic Resonance safety and compatibility (as demonstrated by appropriate testing).

Primary Predicate Device:
The RTI Streamline TL Spinal System is substantially equivalent to the RTI Streamline TL Spinal System in device indications, design, function, materials, and performance.

Table 1: Primary Predicate Devices

Manufacturer	Device Name	K-Number
RTI	Streamline TL Spinal System	K140696

Additional Predicate Device:
The RTI Streamline TL Spinal System is substantially equivalent to the Quantum Spinal Rod System (RTI Surgical, Inc.; K101790) with respect to the subject device's design.

Materials:
The implant components of the Streamline TL Spinal System are manufactured from implant grade Titanium Alloy per ASTM F136. Spinal rods are also available in Cobalt Chromium Alloy per ASTM F1537.

Performance Testing Summary:
Engineering analyses were performed to demonstrate that performance of the Streamline TL Spinal System was equivalent to the cited predicate devices. Additionally, testing was performed to demonstrate bone screw pull-out strength and to confirm MRI compatibility of the system. The testing is summarized below:

- Cortical-Cancellous Bone Screw Testing (Axial Pull-out Strength, Insertion and Removal Torques per ASTM F543-17 / F2193-18)
- Streamline TL II Executive Test Summary (Axial Static Compression testing, Static Torsion testing, Axial Fatigue testing per ASTM F1717-12 / F1798-97)
- Streamline TL Biological Safety Assessment (Genotoxicity and Carcinogenicity per ISO 10993-3, Cytotoxicity per ISO 10993-5, Implantation per ISO 10993-6, Sensitization and Irritation per ISO 10993-10, Acute Systematic Toxicity, Material Mediated Pyrogenicity, Subchronic Systemic Toxicity, and Chronic Systemic Toxicity per ISO 10993-11)
- Streamline TL MRI Conditional Labeling Assessment (Magnetically Induced Displacement Force per ASTM F2052-15, Magnetically Induced Torque per F2213-17, Radio Frequency Induced Heating per F2182-11a, Evaluation of MR Image Artifacts per F2119-07)

Substantial Equivalence:
The Streamline TL Spinal System, with incorporation of the subject components, is substantially equivalent to the predicate in terms of material, design, and indications for use. Engineering analysis was completed for the subject components and demonstrated no pre-clinical performance data was required to demonstrate equivalence of the product. There are no significant differences between the Streamline TL Spinal System and the predicate devices which would adversely affect the use of the product.

The subject devices were demonstrated to be substantially equivalent to predicates cited in the table above with respect to indications, design, materials, function, manufacturing, and performance.

Conclusion:
The RTI Streamline TL Spinal System is substantially equivalent to the cited predicate devices with respect to its indications for use, design, function, materials, and performance.