November 26, 2019

Pioneer Surgical Technology, Inc.
DBA RTI Surgical, Inc.
Michael R. Mach
Senior Regulatory Affairs Specialist
375 River Park Circle
Marquette, Michigan 49855

Re: K192396
Trade/Device Name: Streamline MIS Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: August 30, 2019
Received: September 3, 2019

Dear Mr. Mach:

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,

Ronald P. Jean, Ph.D.
Director (Acting)
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)*

K192396

Device Name
Streamline MIS Spinal Fixation System

Indications for Use *(Describe)*

The Streamline MIS Spinal Fixation System is intended for posterior, noncervical pedicle fixation, T1-S2 or sacral/iliac screw fixation. Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion. The device is indicated for all the following indications: degenerative disc disease (DDD) (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Streamline MIS Instrumentation, when used with the Streamline MIS Spinal Fixation System, is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

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

Date Prepared: August 30, 2019

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Device
Trade Name: Streamline MIS Spinal Fixation System
Common Name: Pedicle Screw Spinal System
Regulation Number: 21 CFR 888.3070 Thoracolumbosacral pedicle screw system
Product Codes: NKB (thoracolumbosacral pedicle screw system)

Product Classification: Class II

Predicate Device
K130286 Streamline MIS Spinal Fixation System

Additional Predicate Device
K140696 Streamline TL Spinal Fixation System

Device Description

Streamline MIS Spinal Fixation System is a temporary, multiple component cannulated pedicle screw system comprised of a variety of components that allow the surgeon to build a spinal implant construct through an open or percutaneous approach. The implant components include rods, extended tab cannulated polyaxial pedicle screws, crosslinks, and locking set screws that are fabricated from titanium alloy (ASTM F136) and provided nonsterile. The components are available in various sizes to accommodate differing patient anatomy. The system is attached to the pedicles by means of screws to the posterior, noncervical spine. The spinal construct is

completed by connecting the screws with titanium alloy rods. Crosslinks can be used if additional stabilization is necessary.

The locking set screw for use with the subject system is the same as that cleared through K130286, and will continue to be labeled with the Streamline TL trade name.

Similarly, the crosslinks used with the subject system were previously cleared as part of predicate system K130286 and will continue to be labeled with their respective trade names, Streamline TL Crosslinks and Quantum X–Links.

The Streamline MIS Spinal Fixation System includes instrumentation to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

Class I manual instruments are also included.

This remains unchanged from K130286.

Indications for Use

The Streamline MIS Spinal Fixation System is intended for posterior, noncervical pedicle fixation, T1-S2 or sacral/iliac screw fixation. Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion. The device is indicated for all the following indications: degenerative disc disease (DDD) (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Streamline MIS Instrumentation, when used with the Streamline MIS Spinal Fixation System, is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

This remains unchanged from K130286 except for addition of “or sacral/iliac screw fixation” in alignment with RTI’s K140696 Streamline TL Spinal Fixation System.

Comparison to Predicate

When compared to the predicate and reference devices, the Pioneer Surgical Technology Streamline MIS Spinal Fixation System presented in this submission have the:

- Same Intended Use
- Same Technological characteristics and Operating principle
- Same Design Features
- Same Performance
- Same Base Materials (stainless steel, titanium)
- Same Shelf Life

Summary of Mechanical Performance Data

Non-standard testing was used to verify the performance characteristics of the instrumentation. Clinical testing was not required to establish substantial equivalence. The subject drivers were tested for torque to failure characterization, characterized the torque required for bone insertion, to show the torque characterization for cannulated driver materials, and to characterize the torque to failure for the breakaway and hexalobe tip redesign features. All testing supports that Streamline MIS Spinal Fixation System is substantially equivalent to the predicate device for safety and efficacy.

Summary of Magnetic Resonance (MR) Safety Evaluation

Standard testing was used to determine appropriate MR labeling of this device. Clinical testing was not required to establish substantial equivalence. The subject system was tested to ASTM F2503-13, ASTM F2502-15, ASTM F2213-17 and ASTM F2182-11a. Testing concluded Streamline Spinal Fixation System is 'MR Conditional' and will be labelled as such.

Conclusion

The information provided in this submission demonstrates that the subject system is substantially equivalent to legally marketed pedicle screw systems with respect to intended use, technological characteristics and performance.