510(k) Summary Pursuant to 21 CFR 807.92

JUN 2 7 2013

Sponsor: Pioneer Surgical Technology, Inc.
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Contact: Sarah McIntyre
Prepared: April 18, 2013

Trade name: Streamline TL Spinal System

Common name: Pedicle Screw System

Classification: 21 CFR 888.3060, Spondylolisthesis Spinal Fixation Device System and 21 CFR 888.3070 Pedicle Screw Spinal System, Class III

Product Codes/ Panel: NKB, KWQ, MNI, MNH
Panel Code 87

Predicates: K111502 Streamline TL Spinal System (SE 8-23-2011)
K130286 Streamline MIS Spinal Fixation System (SE 4-1-2013)
K022949 Synthes USS (SE 3-24-2003)

Description: The Streamline TL Spinal System consists of a variety of rods, screws (poly-axial, fixed, and reduction), transverse connectors, set screws 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. Sacral/iliac screws are designed for posterior fixation. The Streamline TL Spinal System includes Class I manual instrumentation to facilitate implantation of the device components.

The Streamline TL Spinal System may be used with the Streamline TL Crosslink, SpineWorks FixxSure Crosslink or the Quantum® Spinal System X-Link®.

The purpose of this submission is to add components to the System.

Materials: The implant components of the Streamline TL Spinal System are manufactured from the implant grade Titanium Alloy, Grade 23 per ASTM F136. Spinal rods are also available in cobalt chromium alloy per ASTM F1537.

Intended Use: The Streamline TL Spinal System components are non-cervical spinal fixation devices intended as an adjunct to fusion for use as a pedicle screw (T1-S2), sacral/iliac screw fixation or as an anterolateral fixation system (T8 – L5). 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, pseudoarthrosis, and failed previous fusion.

Technological Characteristics:	The subject and predicate systems are overall similar in: - Intended use (described above) - Basic design: rod-based having screw anchors - Materials: Titanium Alloy, Grade 23 per ASTM F136, CCM Alloy per ASTM F1537 - Sizes: dimensions comparable to predicates - Performance: equivalent mechanical test results The fundamental scientific technology of the subject system is the same as predicate devices. There are no significant differences between the Streamline TL Spinal System and the predicate devices which would adversely affect the use of the product.
Pre-Clinical Performance Data:	The subject system was evaluated per ASTM F1717 Static Compression Bending and Static Torsion, and Dynamic Compression Bending Testing and compared to predicate devices. Also, ASTM F1798 testing was performed to evaluate the interconnection mechanisms and subassemblies used in the spinal construct. Testing demonstrated that the device is as safe, as effective and performs as well as or better than the predicate device.
Substantial Equivalence	This submission supports the position that the subject system is substantially equivalent to previously cleared pedicle screw systems based on comparison of indications for use, intended use, materials, technological characteristics, and pre-clinical performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

Pioneer® Surgical Technology, Incorporated
% Ms. Sarah McIntyre
Regulatory Affairs Associate II
375 River Park Circle
Marquette, Michigan 49855

Re: K131100
Trade/Device Name: Streamline TL Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWQ
Dated: June 12, 2013
Received: June 13, 2013

Dear Ms. McIntyre:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K131100

Device Name: Streamline TL Spinal System

Indications:

The Streamline TL Spinal System components are non-cervical spinal fixation devices intended as an adjunct to fusion for use as a pedicle screw (T1-S2), sacral/iliac screw fixation or as an anterolateral fixation system (T8 – L5). 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, pseudoarthrosis, and failed previous fusion.

Prescription Use ___√___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131100