K110692

MAY 12 2011

510(k) Summary

Sponsor:	Pioneer Surgical Technology, Inc. 375 River Park Circle Marquette, MI 49855 (906) 225-5602 Contact: Emily M. Downs Date prepared: April 15, 2011
Device Name:	Streamline TL Spinal System
Classification Name:	888.3060, Spondylolisthesis Spinal Fixation Device System and 888.3070 Pedicle Screw Spinal System, Class III
Product Codes:	NKB, KWQ, MNH, MNI, Panel Code 87
Predicate Device:	K093692 – Streamline TL Spinal System (SE date – August 11, 2010) K081331 – SpineWorks FixxSure Cross Link (SE date – July 23, 2008)
Description:	The Streamline TL Spinal System consists of a variety of rods, pedicle screws, connectors, set screws and other connection components used to build a spinal construct. Cross-links available for use with the Streamline TL system include the Quantum X-Link and the SpineWorks FixxSure Crosslink. The implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Instrumentation is also available to facilitate implant of device components. The purpose of this submission is to include the FixxSure Cross Link to the Streamline TL System. The Cross Link is designed to provide added fixation to the spinal construct and is available in fixed (23 – 28mm) and variable lengths (28 – 66mm).
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, pseudoarthosis, and failed previous fusion.
Material:	Screws, Set Screws, and Connecting components are comprised of Titanium Alloy per ASTM F136. Rods are comprised of Titanium Alloy per ASTM F136 or Cobalt Chromium Molybdenum Alloy per ASTM F1537.
Performance Data:	ASTM F1717 dynamic compression bending, static compression bending and static torsion testing was presented to characterize the performance of the Streamline TL construct with the additional FixxSure Crosslink. The test results demonstrate that the addition of the FixxSure Crosslink to the Streamline TL system functioned as intended and performed in a manner substantially equivalent to that of the predicate system.
Performance and SE Determination:	Comparisons of device performance data, materials, indications and design/function to predicate devices were provided in making a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAY 12 2011

Pioneer Surgical Technology, Inc.
% Ms. Emily M. Downs
375 River Park Circle
Marquette, Michigan 49855

Re: K110692
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, MNH, MNI, KWQ
Dated: April 15, 2011
Received: April 18, 2011

Dear Ms. Downs:

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

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" (21CFR 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,

for

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

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K110692

Device Name: Streamline TL Spinal System

Indications for 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, pseudoarthosis, and failed previous fusion.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110692