3.0 510(k) Summary

Sponsor:

Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855
(906) 225-5602
Contact: Emily M. Downs
Prepared: August 10, 2010

AUG 10 2010

Device Name: Streamline MIS Cannulated System

Classification Name: Spondylolisthesis Spinal Fixation Device System and Pedicle Screw Spinal System – §888.3070, Class II.

Product Codes: Product codes: MNH, MNI; Panel Code 87

Predicate Device: K080026 – Quantum MIS Cannulated System (SE date – 1/28/08)
K072187 – LowTop Spinal Rod System (SE date – 10/12/07)

K080518 - Quantum Spinal System (SE date – 3/20/08)
K080504 - LowTop Spinal Rod System (SE date – 3/20/08)

Description: The Streamline MIS Cannulated System consists of rods, pedicle screws, connectors, and set screws 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 MIS Cannulated System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lower thoracic and/or lumbar spine during open or percutaneous spinal procedures. The implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Screws, Set Screws, Rods and Connecting components are comprised of Titanium Alloy per ASTM F 136.

Intended Use: The Streamline MIS Cannulated System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, trauma (*i.e.,* fracture or dislocation), deformities or curvatures (*i.e.,* scoliosis, kyphosis, and /or lordosis), spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, this device is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine

(L3-S1) with removal of the implants after the attainment of a solid fusion.

Technological Characteristics	The Streamline MIS Cannulated System consists of a range of polyaxial screw lengths and diameters that match that of predicate systems. The rods and connecting components are identical to that of the predicate system. Intended Use and Materials are also identical to that of the predicate systems. Both the Streamline MIS Cannulated and the predicate system use a component (set screw/ cap) that connects to the screw yoke to lock down the rod/ screw head. The mechanism by which this component locks to the screw head is different between the Streamline MIS Cannulated (threaded) and that of the Pioneer predicate system (cam lock).
Performance Data:	Mechanical testing was presented to characterize construct and component performance, including testing static and fatigue compression bending and static torsion per recognized ASTM F1717 as outlined in FDA's "Guidance for Industry and Staff: Spinal Systems 510(k)s" issued May 3, 2004, Additional testing was performed per internal protocols to characterize component performance and included evaluation of crosslink disassociation, saddle/cap separation, and yoke disassociation from screw head. The test results of verification testing demonstrate that the mechanical performance of the Pioneer Streamline MIS Cannulated System is substantially equivalent to the predicate devices.
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

Pioneer Surgical Technology
% Ms. Emily M. Downs
Regulatory Affairs Associate
375 River Park Circle
Marquette, Michigan 49855-0627

AUG 10 2010

Re: K093771
Trade/Device Name: Streamline MIS Cannulated System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: July 30, 2010
Received: August 02, 2010

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 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,

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

Enclosure

K093771

AUG 10 2010

2.0 Indications for Use Statement

510(k) Number (if known): K093771

Device Name: Streamline MIS Cannulated System

Indications for Use:

The Streamline MIS Cannulated System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, trauma (*i.e.*, fracture or dislocation), deformities or curvatures (*i.e.*, scoliosis, kyphosis, and /or lordosis), spinal tumor, and failed previous fusion (pseudoarthrosis).

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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)

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

510(k) Number K093771