510(k) Summary K121725

NOV 7 2012

Sponsor:

Pioneer Surgical Technology, Inc.
375 River Park Circle
Marquette, MI 49855
Contact: Sarah McIntyre or Emily Downs (906) 225-5861
Prepared November 7, 2012

Device Name:

Pioneer Posterior Occipito-Cervico-Thoracic System
(Trade name: Streamline OCT Occipito-Cervico-Thoracic System)

Classification:

Class II per Regulation Numbers §888.3050 Spinal interlaminal fixation orthosis and §888.3070 Pedicle screw spinal system
Product Codes: KWP, MNH, MNI; Panel Code: 87

Predicate Devices:

Pioneer Posterior Cervico-Thoracic System (K112757)
Biomet Spine Nextgen Altius OCT System (K113593)
DePuy Mountaineer OCT (K042508)
Aesculap Spine: S4 Cervical System (K100147)

Description:

The Pioneer Posterior Occipito-Cervico-Thoracic (OCT) System consists of a variety of rods, hooks, polyaxial pedicle screws, high-angle pedicle screws, locking caps, occipital bone screws, occipital plates and connecting components used to build an occipito-cervico-thoracic spinal construct. The purpose of this submission is to introduce occipital plate and connecting components to the previously cleared Pioneer Posterior CT System to expand the indications for the system as a whole and to build an OCT spinal construct.

The Pioneer Posterior OCT System components are manufactured from medical grade ASTM F136 titanium alloy and ASTM F1537 cobalt chromium. Medical grade titanium alloy and cobalt chromium may be used together.

Indications for Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Pioneer Posterior Occipito-Cervico-Thoracic (OCT) System is intended for:

- -Degenerative Disc Disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- -Spondylolisthesis
- -Spinal Stenosis
- -Fracture/ Dislocation
- -Atlanto/axial fracture with instability
- -Occipito-cervical dislocation
- -Deformities or Curvature
- -Tumors
- -Pseudoarthrosis
- -Revision of previous cervical and upper thoracic spine surgery

The occipital bone screws are limited to occipital fixation only. The use of the pedicle screws (standard and high angle) is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The pedicle screws are not intended for use in the cervical spine.

The hooks, connectors, and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/ upper thoracic (C1-T3) spine.

Indications for Use (continued)...	The Pioneer Posterior OCT System can also be linked to FDA cleared pedicle screw systems (e.g., Quantum Spinal Fixation System or Streamline TL Spinal System) using connectors.
Performance Data:	Mechanical testing was conducted in accordance with the FDA's Guidance for Industry and FDA Staff – Spinal System 510(k)s dated May 3, 2004. Per the guidance document, the following testing was conducted: dynamic axial compression, static axial compression dynamic torsion and torsion static testing. Testing was conducted in accordance with ASTM F2706 and ASTM F1798. The test results, along with cadaver studies, computer modeling and dimensional analysis, demonstrate that the Pioneer Posterior OCT System functioned as intended and performed in a manner substantially equivalent to that of predicate systems.
Performance and SE Determination:	Equivalence for the Pioneer Posterior OCT System is based on similarities of intended use, design, and physical characteristics when compared to predicate devices. Therefore, Pioneer Surgical Technology believes that there is sufficient evidence to conclude that the Pioneer Posterior OCT System is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 7, 2012

Pioneeer Surical Technology, Incorporated
% Ms. Sarah McIntyre
Regulatory Affairs Associate
375 River Park Circle
Marquette, Michigan 49855

Re: K121725
Trade/Device Name: Pioneer Posterior Occipito-Thoracic System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP, MNI, MNH
Dated: September 24, 2012
Received: September 26, 2012

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" (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

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): K121725

Device Name: Pioneer Posterior Occipito-Cervico-Thoracic System

Indications: When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3), the Pioneer Posterior Occipito-Cervico-Thoracic (OCT) System is intended for: degenerative disc disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture/ dislocation, atlanto/axial fracture with instability, occipito-cervical dislocation, deformities or curvature, tumors, pseudoarthrosis, and revision of previous cervical and upper thoracic spine surgery.

The occipital bone screws are limited to occipital fixation only. The use of the pedicle screws (standard and high angle) is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The pedicle screws are not intended for use in the cervical spine.

The hooks, connectors, and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/ upper thoracic (C1-T3) spine.

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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

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