MAR - 7 2011

510(k) SUMMARY

Pioneer Quantum Spinal System (including MIS) HA Coated Pedicle Screws (Non-Cannulated and Cannulated)

Sponsor:	Manufacturer	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855
	Official Contact: Phone: Fax:	Emily M. Downs 906-225-5602 906-226-4459
	Representative/ Consultant: Phone: Fax:	Barry E. Sands 978-363-5277 978-477-0206
	Date prepared:	March 7, 2011
Device Name:	Pioneer Quantum Spinal System (including MIS) HA Coated Pedicle Screws (Non-Cannulated and Cannulated)	
Classification Name:	Spinal Interlaminal Fixation Orthosis/ Spinal Intervertebral Body Fixation Orthosis / Pedicle Screw System	
Classification Number:	21 CFR 888.3050: Spinal Interlaminal Fixation Orthosis (Appliance, Fixation, Spinal Interlaminal), Product code KWP, Class II; 21 CFR 888.3060: Spinal Intervertebral Body Fixation Orthosis, Product code KWQ, Class II; and 21 CFR 888.3070(b)(1) & (2): Pedicle Screw Spinal System, Product codes MNH, MNI Class II, NKB Class III.	
Predicate Devices:	Quantum (including MIS) Spinal Implant System Pedicle Screws (K080518, K080026, K070973, K070551 and K041167); Dynesys hydroxyapatite-coated screws (K060638); and TSRH hydroxyapatite-coated screws (K091797).	

Description:

The Quantum Spinal System (including MIS) consists of a variety of rods, fixed and polyaxial screws, transverse connectors, and locking caps used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components.

The Quantum Spinal System (including MIS) are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic and/or lumbar spine. The implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The Quantum Spinal System (including MIS) components are comprised of Titanium Alloy Ti6Al4V per ASTM F136. A subcomponent of the locking cap, a spring clip, is comprised of nitinol (NiTi) per ASTM F 2063. All components of the Quantum Spinal System (including MIS) HA Coated Pedicle Screws (Non-Cannulated and Cannulated) are comprised of Titanium Alloy Ti6Al4V per ASTM F136 and have a hydroxyapatite (HA) coating.

The purpose of this submission is to include HA coated pedicle screws to the Quantum Spinal System (including MIS).

Intended Use:	The Quantum-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. The Quantum Spinal System components are non-cervical spinal fixation devices intended as an adjunct to fusion for use as a pedicle screw system (T1 - S2), posterior hook (T1-L5) 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 regardless of the intended use: 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.
Material:	The Pioneer HA Coated Quantum (including MIS) Spinal System Pedicle Screws (Non-Cannulated and Cannulated) are composed of Ti Alloy per ASTM F136 and hydroxyapatite coating. The predicate device is composed of the same material.
Comparison to Predicate Devices:	The indication for use, material, mechanism of action, and available sizes of the Pioneer HA Coated Quantum Spinal System (including MIS) are within the range of sizes as the predicate device.
Performance Data:	For a determination of substantial equivalence, the following non-clinical mechanical tests were performed: • Pedicle Screw Insertion and Removal Torques • Static Flexion-Extension Test • Dynamic Flexion-Extension of HA Coated and Uncoated Cannulated Screws Existing testing was also provided to demonstrate the requirements of the FDA guidance document "510(k) Information Needed for Hydroxyapatite Coated Implants".
Performance and SE Determination:	Based on the supporting documentation within this premarket notification, the subject device demonstrates substantial equivalence to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Pioneer Surgical Technology
% RQMIS, Inc.
Mr. Barry E. Sands
5 Hemingway Lane
West Newbury, Massachusetts 01985

MAR - 7 2011

Re: K101790
Trade/Device Name: Quantum Spinal System (including MIS)
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: February 28, 2011
Received: March 01, 2011

Dear Mr. Sands:

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,

for

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K101790

Device Name: Quantum Spinal System (including MIS)

Indications:

The Quantum-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.

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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 K101790