510(k) Summary

Date Prepared: 4 November 2010

NOV - 4 2010

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Contact: Bret M. Berry
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Common or Usual Name:	Spinal Fixation Device
Proposed Proprietary or Trade Name:	Reliance Spinal Screw System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis (per 21 CFR 888.3060) Spinal Interlaminal Fixation Orthosis (per 21 CFR 888.3050) Spondylolisthesis Spinal Fixation Device System and Pedicle Screw System (per CFR 888.3070)
Product Code:	KWP, KWQ, MNH, MNI

Substantial Equivalence

The **Reliance Spinal Screw** is substantially equivalent to the legally marketed Reliance Spinal Screw (K081978), Medtronic TSRH Spinal System (K880215, K072429), Medtronic CD Horizon (K961633, K063670), DePuy Expedium Spine System (K041119, K081252), DePuy Isola Spinal System (K905184, K022285), DePuy Viper Spine System (K061520, K073562), DePuy MOSS Miami Spinal System (K933881, K030383), Pioneer Surgical Quantum Spinal System (K070973, K080518), K2M Range Spinal System (K080792), K2M Denali Spinal System (K042635, K052404), K2M Mesa Spinal System (K052398), Interpore Cross Synergy Spinal System (K940631, K041449), Stryker Xia Spinal System (K984251, K080928), X-Spine Capless Pedicle Screw System (K052847, K072282), Synthes Pangea (K052123). The **Reliance Spinal Screw** is equivalent to these commercially available devices in terms of material, intended use, levels of attachment, size range, and strength.

Device Description

The **Posterior RELIANCE Spinal Screw System** consists of longitudinal rods, monoaxial screws, polyaxial screws, reduction screws, cannulated poly axial screws, cannulated reduction screws, hooks, reduction hooks, set screws, transverse connectors.

The **Anterior RELIANCE Spinal Screw System** consists of two spinal rods, monoaxial screws, staples, and set screws. The Anterior RELIANCE staples and screws are intended to be attached to the lateral aspect of the vertebral bodies from T5 to L4, and SHOULD NOT be attached to the anterior aspect. Furthermore, only Titanium components should be used anteriorly. (See Precautions section.)

The **RELIANCE Spinal Screw System** components are available in titanium alloy conforming to ASTM F-136 specifications as well as stainless steel conforming to ASTM F-138 specifications. Furthermore, various rods of the **RELIANCE Spinal Screw System** are available in Cobalt Chrome conforming to ASTM F-75 specifications. Components of the differing diameter rod systems are NOT interchangeable. The components of one material should not be used with components of another material, with the exception that the Cobalt Chrome rods may be used with titanium alloy implants. The extension tabs on the reduction screw and hook components are intended to be removed intraoperatively.

Intended Use/Indications for Use

The **RELIANCE Spinal Screw System** is a pedicle screw systems 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 and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).
The **RELIANCE Spinal Screw System** is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 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 to sacrum) with removal of the implants after the attainment of a solid fusion.
When used posteriorly, the **RELIANCE Spinal Screw System** is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for, spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.
The **RELIANCE Spinal Screw System** when used with staples and two rods as an anterior thoracic/lumbar screw fixation system, is indicated for spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).
When used in a percutaneous, posterior approach with MIS Instrumentation, the **RELIANCE Spinal Screw System** components are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications:spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Non-Clinical Testing
The **RELIANCE Spinal Screw System** has undergone Non-Clinical Testing including Static Compressive, Static Torsion, and Dynamic Compressive in accordance with ASTM F1717. However, the additional components provided in this application have not had additional testing performed on them. A detailed engineering comparison of the subject device to the predicate crosslink has been provided.

Technological Modifications
The subject Reliance Spinal Screw offers a new, simpler 3-point cross-link to the predicate 4-point cross-link. Additionally, 600mm rods have been added to the subject **RELIANCE Spinal Screw System**.

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

Reliance Medical Systems
% Mr. Bret M. Berry
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NOV - 4 2010

Re: K101112
Trade/Device Name: Reliance Spinal Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWP, KWQ, MNH, MNI
Dated: October 27, 2010
Received: October 28, 2010

Dear Mr. Berry:

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

Indications for Use

NOV - 4 2010

510(k) Number (if known): K101112

Device Name: Reliance Spinal Screw System

Indications for Use:

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When used in a percutaneous, posterior approach with MIS Instrumentation, the Reliance Spinal Screw System components are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications:spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K101112