May 13, 2021

Reliance Medical Systems, LLC
Bret Berry
Member-Manager
545 West 500 South, Suite 100
Bountiful, Utah 84010

Re: K210874/S001
Trade/Device Name: Reliance Spinal Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWQ, KWP
Dated: April 7, 2021
Received: April 13, 2021

Dear Bret 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210874

Device Name
Reliance Spinal Screw System

Indications for Use *(Describe)*
The Reliance Spinal Screw System is a pedicle screw system 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 disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), 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 and 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, pseudarthrosis, and failed previous fusion in skeletally-mature patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Reliance Medical Systems, LLC
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Contact	Bret M. Berry Member-Manager Reliance Medical Systems, LLC Phone: (801) 718-7467
Common or Usual Name	Spinal Fixation Device
Proposed Proprietary or Trade Name	Reliance Spinal Screw System
Classification Name	Thoracolumbosacral pedicle screw system (per 21 CFR 888.3070) Spinal Interlaminal Fixation Orthosis (per 21 CFR 888.3050) Spinal Intervertebral Body Fixation Orthosis (per 21 CFR 888.3060)
Product Code	NKB, KWP, KWQ

Substantial Equivalence

The Reliance Spinal Screw is substantially equivalent to the legally marketed primary predicate Reliance Spinal Screw (K162066) and the additional predicate OrthoFix Firebird and JANUS Screw Fixation System (K180179). 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 polyaxial screws, cannulated reduction screws, hooks, reduction hooks, set screws and transverse connectors.
The Anterior Reliance Spinal Screw System consists of 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 and ASTM F-1537 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 system 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 disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), 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 and 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.

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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, pseudarthrosis, and failed previous fusion in skeletally-mature patients.

Non-Clinical Testing

The predicate Reliance Spinal Screw System has undergone Non-Clinical Testing including Static Compressive, Static Torsion, and Dynamic Compressive in accordance with ASTM F1717. The changes and additions to the subject Reliance Spinal Screw System do not represent a new worst case; therefore, no new mechanical performance testing is warranted.

Conclusions

Conclusions drawn from the nonclinical tests and risk analyses demonstrate that the device is as safe and effective as the predicate device.

Technological Modifications

The subject Reliance Spinal Screw offers two new fenestrated screw systems (single and circumferential) for use with saline or radiopaque dye only, a percutaneous screw system, and two bar-end rod systems. These additions will be available in similar sizes, material and configurations as the currently approved Reliance Spinal Screws. The subject Reliance Spinal Screw System is substantially equivalent to the predicate devices in terms of sterilization and biocompatibility.