APR 2 5 2014

510(k) Summary

23 April 2014

Reliance Medical Systems, LLC
545 West 500 South, Suite 100
Bountiful, UT 84010
Telephone: 801-295-3280
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Contact: Bret M. Berry
Member-Manager

510(k) Number:	
Common or Usual Name:	Anterior Cervical Plate
Proposed Proprietary or Trade Name:	Reliance Anterior Cervical Plate System
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Regulation Number:	21 CFR 888.3060
Product Code:	KWQ
Class:	II

Substantial Equivalence
The Reliance Anterior Cervical Plate is substantially equivalent to itself (K122216). The Reliance Anterior Cervical Plate is equivalent to these commercially available devices in terms of material, intended use, levels of attachment, size range, and strength.

Device Description
The Reliance Anterior Cervical Plate System device is intended to be used as an anterior cervical plate device. The Reliance Anterior Cervical Plate System is comprised of implant and instrument components. The Reliance Anterior Cervical Plate implant device is manufactured from Titanium alloy as specified by ASTM F-136. The Reliance Anterior Cervical Plate is a combination of the plate, cover plate, set screw, and bone screw components. The cover plate is attached to the plate by means of the set screw.

Intended Use/Indications for Use
The Reliance Anterior Cervical Plate System is indicated for stabilization of the anterior cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include:

- instability caused by trauma or fracture;
- instability associated with correction of cervical lordosis and kyphosis deformity;
- instability associated with pseudoarthosis as a result of previously failed cervical spine surgery;
- instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine;

- instability associated with single or multiple level corpectomy in advanced degenerative disk disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), spinal canal stenosis and cervical myelopathy.

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Performance Data and Substantial Equivalence

Mechanical testing was performed on the predicate Reliance Anterior Cervical Plate System (K122216) following ASTM F-1717 (static compression bending, static torsion, and dynamic compression bending). The Reliance Anterior Cervical Plate System was found to be substantially equivalent to the predicate devices. Additionally, the Reliance Cervical Plate System is substantially equivalent to the predicate devices in terms of sterilization and biocompatibility. A risk analysis was performed on the subject devices and it was determined that no additional mechanical testing was needed for the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

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

Re: K140742
Trade/Device Name: Reliance Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 26, 2014
Received: March 27, 2014

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 contact 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. 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 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,

Ronald P. Jean -S for

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

Enclosure

Indications for Use

510(k) Number (if known): K140742

Device Name: Reliance Anterior Cervical Plate System

Indications for Use:

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

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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