K113540

MAR 12 2012

510(k) Summary

Date: 8 March 2012

Reliance Medical Systems, LLC
545 West 500 South, Suite 100
Bountiful, UT 84010
Telephone: 801-295-3280
Fax: 801-294-0074

Contact: Bret M. Berry
Member-Manager

510(k) Number:	
Common or Usual Name:	Intervertebral Body Fusion Device
Proposed Proprietary or Trade Name:	Reliance Lumbar IBF System
Classification Name:	Intervertebral Body Fusion Device
Regulation Number:	21 CFR 888.3080
Product Code:	MAX

Substantial Equivalence
The Reliance Lumbar IBF is substantially equivalent to the legally marketed Alphatec NOVEL System (K090782), the Stryker AVS System (K090816), the Globus Patriot System (K093242), the US Surgical Ray Threaded Fusion Cage (P950019), and the Depuy I/F Cage (P960025).The Reliance Lumbar IBF is equivalent to these commercially available devices in terms of material, intended use, levels of attachment, size range, and use with supplemental fixation.

Device Description
The Reliance Lumbar IBF System is comprised of implant and instrument components. The implant component, the Reliance Lumbar IBF device, is a spacer, which inserts between vertebral bodies in the anterior column of the lumbar spine. The spacer is made of PEEK Optima LT1 with Tantalum markers.

Intended Use/Indications for Use
The Reliance Lumbar IBF System, when used as an Intervertebral Body Fusion device, is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

The Reliance Lumbar IBF System, when used as an Intervertebral Body Fusion device is also intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment.

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Performance Data and Substantial Equivalence

Mechanical testing was performed on the worst case Reliance Lumbar IBF device following ASTM Standards. Static and Dynamic Compression testing was performing following ASTM Standard F2077-03, Subsidence Testing was performed following ASTM F2267-04, and Static Push-out Testing was performed following ASTM Draft F-04.25.02.02. The Reliance Lumbar IBF was found to be substantially equivalent to the predicate devices.

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, LLC
% Mr. Bret M. Berry
545 West 500 South, Suite 100
Bountiful, Utah 84010

MAR 12 2012

Re: K113540
Trade/Device Name: LUMBAR IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: February 20, 2012
Received: February 21, 2012

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.

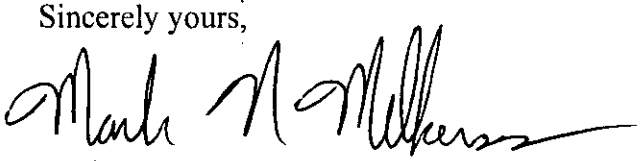
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

510(k) Number (if known): K113540

Device Name: Reliance LUMBAR IBF System

Indications for Use:

The Reliance LUMBAR IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

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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)

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

510(k) Number K113540