January 19, 2018
Reliance Medical Systems, LLC
Bret Berry
Owner
545 West 500 South
Suite 100
Bountiful, Utah 84010

Re: K173283
Trade/Device Name: Reliance Lumbar IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 18, 2017
Received: December 26, 2017

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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173283

Device Name
Reliance Lumbar IBF System

Indications for Use *(Describe)*
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.

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 with patients who have had six months of non-operative treatment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 6: 510(k) Summary

Reliance Medical Systems, LLC
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Suite 100
Bountiful, UT 84010
Telephone: (801) 295-3280
Fax: (801) 294-0079

October 13, 2017

Contact: Bret M. Berry, Member-Manager

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 subject Reliance Lumbar IBF System is substantially equivalent to the legally marketed primary predicate device, the Reliance Lumbar IBF System (K160463). The subject Reliance Lumbar IBF System is equivalent to its predicate in terms of intended use, indications for use, design, function, principle of operation, materials, levels of attachment, and use with supplemental fixation.

Device Description:

The Reliance Lumbar IBF System, originally cleared by FDA in K113540, is intended to be used as an intervertebral body fusion device. Reliance Lumbar IBF device is a spacer, which inserts between vertebral bodies in the anterior column of the thoracic and lumbar spine. The device is surgically implanted between vertebral bodies from an anterior, lateral, or posterior surgical approach. The Reliance Lumbar IBF device will be manufactured from PEEK. The PEEK device also contains Tantalum wires to aid in fluoroscopic visualization. The construct is not intended to be employed as a standalone device. The Reliance Lumbar IBF is to be used with supplemental fixation in all applications.

Intended Use / 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.

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.

Technological Modifications:

The subject Reliance Lumbar IBF system offers additional implant and instrument components. These include additional implant sizes for use in the Lumbar IBF System, specifically the 10x22, 30x26, 34x27, 45x18, 50x18, 55x18, 55x22, and 60x26mm implant sizes. Additional instruments submitted here as accessories to the Reliance Lumbar IBF System are the Reliance Lumbar Graft Impactor and the Reliance Lumbar Graft Block and Double Graft Block. Finally, the 45x18, 50x18, 55x18, 60x18, 45x22, 50x22, 55x22, 60x22, 60x24, and 60x26mm implant sizes have been made stronger by increasing the teeth depth on the superior and inferior surfaces.

There have been no changes to intended use, indications for use, function, principle of operation, materials, levels of attachment, method of insertion, or labeling.

Performance Data and Substantial Equivalence:

Based on risk analysis for the new implant sizes and design verification testing conducted on the Reliance Lumbar IBF System instruments, it was determined that the inclusion of these implants and instruments into the Reliance Lumbar IBF System does not create a new worst-case test condition for mechanical testing, performance testing, sterilization, biocompatibility, cleaning or packaging. Therefore, in accordance with the design control process, additional performance data was not necessary for the changes subject of this Special 510(k).

Conclusion

The Reliance Lumbar IBF System is substantially equivalent to the identified predicate device.