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

February 15, 2019

Re: K183049
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: January 16, 2019
Received: January 18, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Katherine D. Kavlock -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)*
K183049

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 in 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Bret M. Berry
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Bountiful, UT 84010
Telephone: 801-388-0700
Fax: 801-294-0079

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:	Class II, Intervertebral Body Fusion Device 21 CFR 888.3080
Product Code:	MAX
Date:	02/15/2019

Substantial Equivalence
The Reliance Lumbar IBF is substantially equivalent to the legally marketed, primary predicate device, Reliance Lumbar IBF System (K180687). The subject Relianace Lumabr IBF System is also substantially equivalent to the additional predicate devices, Reliance Lumbar IBF System (K113540, K160463, and K173283). Subject devices differ in terms of additional size configurations.
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 either made of PEEK OPTIMA LT1 with Tantalum markers or with PEEK OPTIMA LT1-HA with Tantalum markers.

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.

Non-Clinical Testing

The subject implants does not create a new worst case condition for mechanical testing or performance testing. Finite Element Analysis has been carried out to access the effect of new sizes on the structural properties of the implant. Test results show the new components are not the new worst case when compared to the approved Reliance Lumbar IBF PEEK, 1-04-XXX, per K113540.

Technological Modifications

The subject Reliance Lumbar IBF system offers additional components. These new components differ in size.
All implants under Reliance Lumbar IBF System which are intended to be sold sterile, will be sterilized using Gamma Irradiation before shipping.
The subject Relianace Lumabr IBF System will have same indication of use as the currently approved Reliance Lumbar IBF System (K113540, K160463, K173283, and K180687).

Conclusion

The subject implants does not create a new worst case condition for mechanical testing, performance testing, sterilization, biocompatibility, cleaning or packaging. Sterilization method for subject components intended to be sold sterile, was validated.