March 29, 20222

Reliance Medical Systems, LLC
Bret Berry
Owner
P.O. Box 1693
Bountiful, Utah 84010

Re: K202266
Trade/Device Name: Reliance Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 24, 2022
Received: February 28, 2022

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,

for
Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202266

Device Name
Reliance Cervical IBF System

Indications for Use *(Describe)*
The Reliance Cervical IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system devices 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 Cervical IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical degenerative disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The Reliance Cervical IBF System is to be used in patients who have six weeks 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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510(k) Summary

Reliance Medical Systems, LLC
545 West 500 South
Suite 100
Bountiful, UT 84010
Telephone: (801) 295-3280
Fax: (801) 294-0079

29 March 2022

Contact: Bret M. Berry, Member-Manager
510(k) Number: K202266
Common or Usual Name: Intervertebral Body Fusion Device
Proposed Proprietary or Trade Name: Reliance Cervical IBF System
Classification Name: Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Product Code: ODP

Substantial Equivalence:
The subject Reliance Cervical IBF System is substantially equivalent to the legally marketed predicate devices, the Reliance Cervical IBF System (K120396/K131429/K142269/K172489/ K173102, with K173102 as the primary predicate) and the Nexxt Spine Matrixx System (K171140). The subject Reliance Cervical IBF System is equivalent to its commercially available predicates in terms of intended use, indications for use, design, function, principle of operation, materials, levels of attachment, size range, strength and use with supplemental fixation.

Device Description:
The Reliance Cervical IBF System is comprised of implant and instrument components. The implant component, the Reliance Cervical IBF device, is a spacer which inserts between vertebral bodies in the anterior column of the cervical spine. The subject Reliance Cervical IBF spacer is additively manufactured from Titanium 6Al-4V ELI as specified in ASTM F3001, with predicate spacers manufactured from PEEK Optima LT1 or PEEK Optima LT1-HA.

Intended Use / Indications for Use:
The Reliance Cervical IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The system devices 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 Cervical IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical degenerative disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The Reliance Cervical IBF System is to be used in patients who have six weeks of non-operative treatment.

Technological Modifications:
The subject Reliance Cervical IBF system offers intervertebral body spacers in an additional material, Titanium 6Al-4V ELI. There have been no changes to intended use, indications for use, function, principle of operation, sizes or size range, levels of attachment, or method of insertion.

Performance Data and Substantial Equivalence:
The Reliance Cervical IBF device was subjected to performance testing that followed ASTM F2077-18 and F2267-04 (2018) standards. Additionally, the porous lattice structures within the implants presented a new worst-case scenario for sterilization, cleaning and packaging. Therefore, packaging testing was performed according to the following ASTM standards: D4169, D4332, F88, F1886 and F2096, and cleaning validation in accordance to the following ASTM standards: F2459 and F2847. Sterilization validation was performed to the following standards: ANSI/AAMI/ISO 11137-1:2006/A1:2013/A2:2019, ANSI/AAMI/ISO 11137-2:2013, ANSI/AAMI/ISO 11737-1:2006, ANSI/AAMI/ISO 11737-2:2009, and ANSI/AAMI/ISO TIR13004:2013. The Reliance Cervical IBF System is substantially equivalent to the predicate devices in terms of biocompatibility.