July 2, 2020

Benvenue Medical, Inc.
% Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K193172
Trade/Device Name: Luna XD Ti Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 3, 2020
Received: June 3, 2020

Dear Justin Eggleton:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193172

Device Name
Luna XD Ti Interbody Fusion System

Indications for Use *(Describe)*
The Luna XD Ti Interbody Fusion System consists of the Luna XD Ti Implant and associated accessories. This system is indicated for spinal fusion procedures in skeletally mature patients with symptomatic degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). The Luna XD Ti Interbody Fusion System is to be used with autogenous bone graft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients receiving the device should have had at least six months of nonoperative treatment prior to receiving the Luna XD Ti Implant. The Luna XD Ti Interbody Fusion System is to be used with supplemental fixation.

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.

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4 510(k) Summary

Device Trade Name: Luna XD Ti Interbody Fusion System

Manufacturer:
Benvenue Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, California 95054 USA

Contact:
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CTO and Founder
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Prepared by:
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Date Prepared: November 15, 2019

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: MAX

Primary Predicate: The subject devices are substantially equivalent to the following primary predicate device.

Table 6: Primary Predicate Device

Manufacturer	Device Name	K Number
Benvenue Medical	Luna 3D Interbody Fusion System	K183560

Additional Predicates: In addition to the primary predicate device, additional predicate devices cited in this 510(k) are presented in the following table.

Table 7: Additional Predicate Device

Manufacturer	Device Name	K-Number
Exatech	Octane Straight IFD, Ti Coated	K150152

Device Description:
The Benvenue Luna XD Ti Interbody Fusion System consists of the Luna XD Ti Implant and associated accessories set of disposable accessories for use in lumbar fusion procedures to treat degenerative disc disease. The proposed indications for use for the Luna XD Ti Interbody Fusion System are identical to the primary predicate device. The Luna XD Ti Implant is provided pre-loaded and sterile within a single-use Insertion Tool.

The Luna XD Ti Implant is an assembly of three (3) PEEK components referred to as the Top, Middle and Bottom, similar to the Luna 3D Gen2. Additionally, a Nitinol Spine is inserted into the middle component to retain its normally closed shape configuration. And finally, the outer top and bottom surfaces of the implant XD Ti have a commercially pure (Cp) Ti metallic powder. The final components have radiopaque tantalum markers for fluoroscopic visibility.

The outer surfaces of the Top and Bottom components have teeth in addition to the already rough surface created by the Ti coating, which are designed to enhance the implant's resistance to expulsion. Upon insertion of the outer components, the middle component is inserted to expanded into its ultimate height. The central cavity of the implant accommodates placement of autogenous bone graft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft through a graft window.

The Luna XD Ti Implant is manufactured from polyetheretherketone (Evonik VESTAKEEP i4R; ASTM F2026), Nitinol (nickel titanium alloy; ASTM F2063), tantalum (ASTM F560) and commercially pure (Cp) Ti metallic powder coating layer (ASTM F 1580).

The Luna XD Ti Implant is available in heights ranging from 10mm to 14mm with 2mm increments and a 6° lordotic angle and from 12mm to 16mm with 2mm increments and a 12° lordotic angle. A series of vertically oriented slots allows the device to flex and enables it to be inserted from a straight cannula and then attain a closed, fixed, and circular shape upon being placed into the disc space with a bone graft pocket. Teeth engage the implant into the adjacent endplates. In addition, the outer top and bottom surfaces of the implant XD Ti have a commercially pure (Cp) Ti metallic powder conforming to ASTM F1580 with a specified grain size and morphology. This additional titanium coating offers initial stability due to increased surface roughness and possibly also long-term stability due to bony ingrowth created from osteoconductive microenvironment on the device surface.

The Luna XD Ti Implant that is the subject of this 510(k) is manufactured from polyetheretherketone (Evonik VESTAKEEP i4R; ASTM F2026), Nitinol (nickel titanium alloy; ASTM F2063), tantalum (ASTM F560) and commercially pure (Cp) Ti metallic powder coating layer (ASTM F 1580). This 510(k) is submitted in support of the additional surface coating to an existing Device cleared under K183560.

Indications for Use:
The Luna XD Ti Interbody Fusion System consists of the Luna XD Ti Implant and associated accessories. This system is indicated for spinal fusion procedures in skeletally mature patients with symptomatic degenerative disc disease (DDD) at one or two

contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). The Luna XD Ti Interbody Fusion System is to be used with autogenous bone graft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients receiving the device should have had at least six months of nonoperative treatment prior to receiving the Luna XD Ti Implant. The Luna XD Ti Interbody Fusion System is to be used with supplemental fixation.

Performance Testing Summary:
Mechanical testing was completed by confirmation testing of runouts in Axial Compression, Torsion, and Compression-Shear at the same load as predicate device to ensure that the coating process does not impact mechanical performance and leverage of the predicate data as the failure modes across all mechanical tests is identical in this regard. Coating thickness, porosity, and surface roughness were characterized according to ASTM F1854 standards. Additional testing of the modified surface (on coupons) were conducted per the following Standards: ASTM F1160 Shear Strength; ASTM F-1044 Static Shear Strength; ASTM F-1147 Tensile Strength and ASTM 1978-99 Abrasion Resistance.

In addition, Debris Analysis per ASTM F1877 was conducted on the Luna XD Ti PEEK implant coated with commercially pure Titanium following testing per ASTM F2077 as well as following implantation testing. The results demonstrate that the devices are substantially equivalent to the predicate devices.

Sterilization, Shelf Life, Cleaning and Pyrogenicity:
The components of the Luna XD Ti Interbody Fusion System are provided sterile. Gamma radiation is utilized for sterilization of the components. All sterile components have a 10^{-6} sterility assurance level. The Luna XD Ti Accessories are provided non-sterile in a sterilization instrument tray (LUN6310) and are the same as previously presented in the predicate device (K183560).

Substantial Equivalence Summary:
Comparative information presented in the 510(k) supports the substantial equivalence of the Luna XD Ti Interbody Fusion System to the primary predicate device. Comparisons were designed to show the indications, intended use, design, and performance are equivalent between the Benvenue Luna XD Ti Interbody Fusion System and primary predicate device.

Conclusion:
The information and performance data demonstrate that the device is as safe, as effective, and performs as well as or better than the primary predicate device. This 510(k) was submitted on behalf of the Luna XD Ti Interbody Fusion System in support of the additional surface coating to an existing Device cleared under K183560. Substantial equivalence was determined in response to sufficient comparisons to the primary predicate device.