Benvenue Medical, Inc.
% Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

May 23, 2019

Re: K183560
Trade/Device Name: Luna 3D GEN2 Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: April 25, 2019
Received: April 26, 2019

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/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,

for
CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*

K183560

Device Name

Luna 3D GEN2 Interbody Fusion System

Indications for Use *(Describe)*

The Luna 3D GEN2 Interbody Fusion System consists of the Luna 3D 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 3D GEN2 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 3D GEN2 Implant. The Luna 3D GEN2 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 3D GEN2 Interbody Fusion System

Manufacturer:
Benvenue Medical, Inc.
4590 Patrick Henry Dr.,
Santa Clara, California 95054 USA

Contact:
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CTO and Founder
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Date Prepared: December 20, 2018

Classifications: 21 CFR §888.3080, Intervertebral body fusion device

Class: II

Product Codes: MAX

Primary Predicate Device: Benvenue Medical Luna 3D Interbody Fusion System (K162431)

Indications for Use:
The Luna 3D GEN2 Interbody Fusion System consists of the Luna 3D 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 3D GEN2 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 3D GEN2 Implant. The Luna 3D GEN2 Interbody Fusion System is to be used with supplemental fixation.

Device Description:
The Benvenue Luna 3D GEN2 Interbody Fusion System consists of the Luna 3D GEN2 Implant and associated accessories set of disposable and re-usable accessories for use in lumbar fusion procedures to treat degenerative disc disease. The proposed indications for use for the Luna 3D GEN2 Interbody Fusion System are identical to the primary predicate device. The Luna 3D GEN2 Implant is provided pre-loaded and sterile within a single-use Insertion Tool.

The Luna 3D GEN2 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. Once the implant is in the desired position, the device is expanded into its ultimate height and forming a bone graft pocket. Teeth on the outer surfaces of the top and bottom components engage the implant into the adjacent endplates.

The Luna 3D GEN2Implant that is the subject of this 510(k) is manufactured from polyetheretherketone (VESTAKEEP i4R, conforming to ASTM F2026), nitinol wire (superelastic alloy SE508, conforming to ASTM F2063) and tantalum rod conforming to ASTM F560. This 510(k) was submitted in support of the Generation 2 device.

Performance Testing:
The worst-case devices were subjected to mechanical testing. Testing included static compression, static compression-shear, static torsion, static modified compression-shear, dynamic compression, dynamic compression-shear, dynamic torsion, expulsion, and subsidence per ASTM F2077-14 and F2267-04. In addition, corrosion testing was completed according to ASTM F2129 and nickel leaching quantitative ICP/MS analysis was performed. A surgical technique validation in cadaver specimens was also performed. The results demonstrate that the Luna 3D GEN2 Interbody Fusion System device is substantially equivalent to the predicate devices.

Substantial Equivalence Summary:
Comparative information presented in the 510(k) supports the substantial equivalence of the Luna 3D GEN2 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 3D GEN2 Interbody Fusion System and primary predicate device and additional predicate devices.

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 3D GEN2 Interbody Fusion System in support of the next generation device design. Substantial equivalence was determined in response to sufficient comparisons to the primary predicate device.