DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 17, 2016

Benvenue Medical, Inc.
% Mr. Justin Eggleton
Senior Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

Re: K162431
Trade/Device Name: Luna 3D Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 26, 2016
Received: August 31, 2016

Dear Mr. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162431

Device Name

Luna 3D Interbody Fusion System

Indications for Use *(Describe)*

The Luna 3D 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 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 Implant. The Luna 3D 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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5. 510(k) Summary

Device Trade Name: Luna 3D Interbody Fusion System

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

510(k) Owner:
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Application Correspondent:
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Date Prepared: August 25, 2016

Classifications: 21 CFR §888.3080: Intervertebral body fusion device

Class: II

Product Codes: MAX

Primary Predicate Device: Orthofix FORZA PTC SYSTEM (K152475)

Additional Predicate Device: Benvenue Medical Luna 360 Interbody Fusion System (K142023)

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

Device Description:
The Benvenue Luna 3D Interbody Fusion System consists of the Luna 3D 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 3D Interbody Fusion System are identical to predicate interbody lumbar cages. The Luna 3D Implant is provided pre-loaded and sterile within a single-use Insertion Tool.

The Luna 3D Implant is available in heights ranging from 8mm to 15mm in 1mm increments. 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.

The Luna 3D Implant is manufactured from polyetheretherketone (PEEK Optima LT-1 or Evonik VESTAKEEP i4R), stainless steel, tantalum, and silicone lubricant (NuSil MED-360).

These design features were demonstrated to be equivalent to the predicate devices presented in the next section.

Performance Testing:
A comprehensive clinical literature review was conducted to assess any additional safety concern for the use of this device with the use of allograft in the lumbar spine. The review of the literature concluded that there were no additional risks due to the modification of indications for this device and that the device was substantially equivalent to the predicate devices.

This 510(k) also incorporates a series of minor design changes, including the addition of an 8-degree lordotic version of the Luna 3D Implant, expansion of the range of the implant height to 15mm, use of Evonik VESTAKEEP PEEK, and an alternative version of the trial instrument known as the Scout. To evaluate the impact of these changes on product performance, procedural validation and bench verification testing was conducted. The bench testing included static/dynamic compression, static/dynamic shear-compression, and static/dynamic torsion tests per ASTM F2077 as well as subsidence testing per ASTM F2267. The results of these tests confirmed that this design is substantially equivalent to legally marketed predicate devices.

Substantial Equivalence Summary:
Comparative information presented in the 510(k) supports the substantial equivalence of the Luna 3D Interbody Fusion System to the following predicate devices: Orthofix FORZA PTC SYSTEM (K152475) and Benvenue Medical Luna 360 Interbody Fusion System (K142023). Comparisons were designed to show the indications, intended use, design, and performance are equivalent between the Benvenue Luna 3D Interbody Fusion System and 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 predicate devices. This 510(k) was submitted on behalf of the Luna 3D Interbody Fusion System to expand the indications for use to include use with allograft in lumbar interbody fusions. Substantial equivalence was determined in response to sufficient comparisons to a predicate device.