DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 29, 2016

Orbbo Surgical, LLC
% Tamala Wampler
Regulatory and Quality Consultant
Novus Management Group, LLC.
6686 Dimmick Road
West Chester, Ohio 45069

Re: K163180
Trade/Device Name: Hubble II
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 25, 2016
Received: November 14, 2016

Dear Ms. Wampler:

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,

Caroline Rhim -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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K163180

Device Name
Hubble II

Indications for Use *(Describe)*

The Hubble II Lumbar Interbody Fusion System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Hubble II System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment. The Hubble II System must be used with supplemental fixation cleared by FDA for use in the lumbar spine.

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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510(K) SUMMARY

Submitter's Name:	Orbbo Surgical, LLC
Submitter's Address:	555 W. 5th Street, 35th Floor Los Angeles, California 90013
Submitter's Telephone:	213-282-3662
Company Contact Person:	Eric Garofano
Contact Person:	Tamala J. Wampler Novus Management Group, LLC. 513-593-4944
Date Summary was Prepared:	October 25th, 2016
Trade or Proprietary Name:	Hubble II
Common or Usual Name:	Intervertebral body fusion device
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices
Panel Code:	87

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Hubble II Lumbar Interbody Fusion System consist of 3 designs, PLIF & PLIF BS, TLIF and OLIF. The PLIF and TLIF implants are available as a lordotic form, while the OLIF implants are provided with no lordosis. The implants are available in various heights and lengths to accommodate patients' anatomy. The implants are provided sterile, and a set of instrument for implantation is provided to facilitate implantation. Two radiographic markers made of tantalum per ASTM F560 are included in the PLIF and OLIF PEEK implants, and three radiographic markers made of tantalum per ASTM F560 are included in the TLIF PEEK implant to allow radiographic visualization.

INDICATIONS FOR USE

The Hubble II Lumbar Interbody Fusion System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Hubble II System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment. The Hubble II System must be used with supplemental fixation cleared by FDA for use in the lumbar spine.

PREDICATES

Hubble II is made PEEK-Optima LT1. The subject and predicate device have identical technological characteristics. The Twin Peaks, the primary predicate is identical to the Hubble II with the exception of it being marketed by a different company under a different product name. Specifically, the following characteristics are identical between the subject and secondary predicates:

- Indications for Use (identical)
- Materials of manufacture (identical)
- Structural support mechanism (identical)

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Type**
K152355	Twin Peaks	Spineway	Primary

PERFORMANCE TESTING

The Hubble II Lumbar Interbody Fusion System was evaluated to demonstrate equivalence to the predicate device. The predicate was tested according to ASTM F2077 and ASTM F2267. Testing included static and dynamic axial compression, static and dynamic compression shear per ASTM F2077-14, subsidence per ASTM F2267-04 and expulsion per a recognized industry standard. As there are no changes in design or materials or manufacturing processes, no new performance testing was required. No clinical or animal studies were performed.

CONCLUSION

Orbbo concludes that the Hubble II Lumbar Interbody Fusion System raises no new questions of safety and effectiveness and is substantially equivalent to the predicate devices.