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

April 7, 2017

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

Re: K163265
Trade/Device Name: Kepler II
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 3, 2017
Received: March 7, 2017

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,

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 on last page.

510(k) Number *(if known)*
K163265

Device Name
Kepler II

Indications for Use *(Describe)*

The Kepler II is indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. These patients should have had 6 weeks of non-operative treatment. The Kepler II implants are to be used with autogenous bone graft and implanted via an open, anterior approach. The Kepler II Cervical Cage 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)*

510(K) SUMMARY

Submitter's Name:	Orbbo, LLC. (Orbbo Surgical, LLC.)
Submitter's Address:	555 W. 5th Street, 35th Floor Los Angeles, CA 90013
Submitter's Telephone:	(800) 942-1880
Company Contact Person:	Eric Garofano CEO
Contact Person:	Tamala J. Wampler Novus Management Group, LLC. 513-593-4944
Date Summary was Prepared:	11/13/2016
Trade or Proprietary Name:	Kepler II
Common or Usual Name:	Intervertebral body fusion device
Classification:	Class II per 21 CFR §888.3080
Product Code:	ODP
Classification Panel:	Division of Orthopedic Devices
Panel Code:	87

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Kepler II Cervical Cage consists of cervical spinal interbody fusion devices as well as instrumentation designed specifically for the implantation of these devices. The Kepler II Cervical Cage is manufactured from PEEK-OPTIMA LT1 polymer and contains tantalum radiopaque markers. The Kepler II Cervical Cage is for single level anterior spinal use from the C2-C3 to C7-T1 disc levels.

INDICATIONS FOR USE

The Kepler II is indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. These patients should have had 6 weeks of non-operative treatment. The Kepler II implants are to be used with autogenous bone graft and implanted via an open, anterior approach. The Kepler II Cervical Cage is to be used with supplemental fixation.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The subject device is substantially equivalent to the predicates. The subject device is equivalent to the predicates in regards to technological characteristics including design, indications for use, intended use, material composition, and function.

PREDICATES

Kepler II is made PEEK-OPTIMA LT1. The subject and predicate devices have identical technological characteristics. Specifically, the following characteristics are identical between the subject and 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**
K112801	Ayers Rock	Qualgenix	Primary
K161407	Ascential IBD PEEK[c] Spacer	Stryker Spine	Additional

PERFORMANCE TESTING

Orbbo, LLC. Kepler II was evaluated to demonstrate equivalence to the predicate devices. Mechanical testing, which characterized the mechanical performance and fatigue endurance to show the original performance requirements for Static Compression, Static Compression Shear, Static Torsion, Dynamic Compression, Dynamic Compression Shear and Dynamic Torsion per ASTM F2077-14, Subsidence per ASTM F2267-04 (reapproved 2011) and Expulsion testing per a recognized industry norm were met. No clinical testing was performed. Bacterial endotoxin testing per USP34 and NF 29. Material-mediated pyrogenicity per ISO 10993-11 (2006) and ASTM F750-87 (2007).

CONCLUSION

The Kepler II has been tested per ASTM F2077 in Static Compression, Static Compression Shear, Static Torsion, Dynamic Compression, Dynamic Compression Shear, Dynamic Torsion and ASTM F2267 Subsidence as well as expulsion testing and were considered substantially equivalent to other legally marketed devices. The subject Kepler II has similar intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The overall technology characteristics lead to the conclusion that the Kepler II is substantially equivalent to the predicate devices.