DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 16, 2017

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

Re: K163602
Trade/Device Name: Kepler I Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 20, 2016
Received: December 21, 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,

Lori A. Wiggins -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)*
K163602

Device Name
Kepler I Cervical Plate System

Indications for Use *(Describe)*

The Kepler I Cervical Plate System is intended for anterior screw fixation at the vertebral bodies of the cervical spine (C2-C7). The Kepler I Cervical Plate System is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, deformity (defined as kyphosis, lordosis, and scoliosis), trauma (including fractures), tumors, pseudoarthrosis, and/or failed previous fusions.

This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. The device is intended for anterior cervical intervertebral body fusions only.

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)*

5. 510(K) SUMMARY

Submitter's Name:	Orbbö, LLC. (Orbbö 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:	12/19/2016
Trade or Proprietary Name:	Kepler I Cervical Plate System
Common or Usual Name:	Spinal Fixation Device
Classification:	Class II per 21 CFR §888.3060 Spinal Intervertebral body fixation orthosis
Product Code:	KWQ
Classification Panel:	Division of Orthopedic Devices
Panel Code:	87

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Kepler I Cervical Plate System is a system that includes titanium alloy (per ISO 5832-3) plates and screws that are intended to stabilize the spine during the fusion process. The plates and screws are available if various sizes to accommodate patients' anatomy. The plates are contoured to follow the curves of the cervical spine.

INDICATIONS FOR USE

The Kepler I Cervical Plate System is intended for anterior screw fixation at the vertebral bodies of the cervical spine (C2-C7). The Kepler I Cervical Plate System is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, deformity (defined as kyphosis, lordosis, and scoliosis), trauma (including fractures), tumors, pseudoarthrosis, and/or failed previous fusions.

This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. The device is intended for anterior cervical intervertebral body fusions only.

PREDICATES

Kepler I Cervical Plate System is substantially equivalent to the Blue Mountain Cervical Plate System (K150036). The subject and predicate devices have identical technological characteristics. Specifically, the following characteristics are identical between the subject and predicate:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Type**
K150036	Blue Mountain Cervical Plate System	Spineway	Primary

TECHNOLOGICAL CHARACTERISTICS

The Kepler I Cervical Plate System is the same as the predicate device. The materials, screw type, screw diameters and lengths, plate widths, thickness and lengths, and screw locking mechanism is the same as the predicate device.

PERFORMANCE TESTING

Kepler I Cervical Plate System was evaluated to demonstrate equivalence to the predicate devices. Mechanical testing (static and dynamic compression testing and static torsion testing per ASTM F1717-10), which characterized the performance of the predicate was not required to be repeated. There are no changes in design, materials or manufacturing processes.

CONCLUSION

Kepler I Cervical Plate System has the same intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The overall technology characteristics lead to the conclusion that the Kepler I Cervical Plate System is substantially equivalent to the predicate devices.