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

February 9, 2017

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

Re: K163566
Trade/Device Name: Hubble I System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: December 14, 2016
Received: December 19, 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,

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)*
K163566

Device Name
Hubble I System

Indications for Use *(Describe)*

The Hubble I System is indicated for use for noncervical pedicle fixation from the T1 to S1 vertebrae in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

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:	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:	12/13/2016
Trade or Proprietary Name:	Hubble I System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070
Product Code:	NKB, KWP
Classification Panel:	Division of Orthopedic Devices
Panel Code:	87

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Orbbo Hubble I System is an implant device made from a titanium alloy Ti 6Al-4V ELI per ISO 5832-3 and Cobalt-Chrome per ISO 5832-12. The titanium alloy implants are provided sterile. The cobalt-chrome implants are provided non-sterile. It is to be implanted from the posterior approach. The screws are available as monobloc and monobloc reduction (traction) screws and polyaxial and polyaxial reduction (traction) screws in diameters from 4.0 - 8.0 mm and in lengths from 25 - 55 mm and polyaxial iliac screws of 7 and 8mm diameters with lengths from 55mm to 110mm. Rods are available in 5.5mm diameter in lengths from 40 - 500 mm. Hooks are available in various sizes to attach to the thoracic and lumbar spine. Transverse connectors are available in various sizes to attach to the two parallel rods. Associated instrumentation to complete the procedure is provided non-sterile.

INDICATIONS FOR USE

The Hubble I System is indicated for noncervical pedicle fixation from the T1 to S1 vertebrae in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

PREDICATES

Hubble I System is substantially equivalent to the Mont Blanc Spinal System (K150185) and is provided sterile as was cleared in Mont Blanc Spinal System (K161387). The Hubble I System also includes bullet shaped rods, pre-bent rods and cobalt-chrome rods cleared in Mont Blanc Spinal System (K161387). The subject and predicate devices have identical technological characteristics. Specifically, the following characteristics are identical between the subject and predicates:

- Indications for Use (identical to Primary)
- Materials of manufacture (identical to Primary and Additional)
- Structural support mechanism (identical to Primary and Additional)

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Type**
K150185	Mont Blanc Spinal System	Spineway	Primary
K161387	Mont Blanc Spinal System	Spineway	Additional

PERFORMANCE TESTING

Orbbo, LLC. Hubble I System was evaluated to demonstrate equivalence to the predicate devices. Mechanical testing was performed for the predicate devices, which characterized the mechanical performance and fatigue endurance to show the original performance requirements for Static Compression Bend, Static Torsion and Dynamic Compression Bend per ASTM F1717-13. 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 I System is substantially equivalent to the predicates in regard to indications for use, materials, function, sizes and mechanical test results and raises no new questions of safety or effectiveness.