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 22, 2016

Eden Spine, LLC
℅ Ms. Tamala Wampler
Regulatory and Quality Consultant
Novus Management Group, LLC
6686 Dimmick Road
West Chester, Ohio 45069

Re: K160982
Trade/Device Name: Sphynx™
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 26, 2016
Received: November 30, 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 yours,

Vincent J. Devlin -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 below.

510(k) Number *(if known)*
K160982

Device Name
Sphynx™

Indications for Use *(Describe)*
The antero-lateral plate Sphynx™ is designed for use during surgery on the thoraco-lumbar area of the spine (T1-L5). The device is to be used only on one side and placed in such a manner as to be as far away from blood vessels and nerve roots as possible.

This implant is intended to provide stabilization until a solid spinal fusion develops, in the treatment of the following indications:

- Tumor of the vertebral body
- Fracture of the anterior spine (trauma)
- Degenerative disc disease, compatible with a ventral approach (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.)
- Pseudoarthrosis
- Spondylolysis
- Spondylolisthesis
- Scoliosis
- Lordotic deformities of the spine
- Spinal stenosis
- Failed previous spine surgery

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(K) SUMMARY

Submitter's Name:	Eden Spine LLC
Submitter's Address:	377 Maitland Avenue, Suite 1015 Altamonte Springs, Florida 32701
Submitter's Telephone:	407-900-9986
Company Contact Person:	Mr. Guillaume Viallaneix CEO
Contact Person:	Tamala J. Wampler Novus Management Group, LLC. 513-593-4944
Date Summary was Prepared:	15 March 2016
Trade or Proprietary Name:	Sphynx™
Common or Usual Name:	Thoracolumbar Plates
Classification:	Class II per 21 CFR §888.3060
Product Code:	KWQ
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Sphynx™ is an implant device made from a titanium alloy Ti-6Al-4V ELI. It is to be implanted from the anterior-lateral approach. The Sphynx™ implant is an antero-lateral plate aimed at performing internal fixation of the thoraco-lumbar area of the spine (T1-L5), in addition to a solid intervertebral arthrodesis. The Sphynx™ instrumentation is composed of plates with anatomical conformation for cyphosis and lordosis. These plates are available in lengths 45-135mm increasing increments of 10mm. The fixation screws also consist of a variety of lengths and diameters. The safety screw is a 5mm diameter screw available in lengths starting at 24mm increasing in increments of 5mm to an overall length of 55mm. The two other fixation screws are available in diameters of 6mm and 7mm starting at 25mm and increasing in increments of 5mm to an overall length of 60mm.

INDICATIONS FOR USE

The antero-lateral plate Sphynx™ is designed for use during surgery on the thoraco-lumbar area of the spine (T1-L5). The device is to be used only on one side and placed in such a manner as to be as far away from blood vessels and nerve roots as possible.

This implant is intended to provide stabilization until a solid spinal fusion develops, in the treatment of the following indications:

- Tumor of the vertebral body
- Fracture of the anterior spine (trauma)
- Degenerative disc disease, compatible with a ventral approach (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.)
- Pseudoarthrosis
- Spondylolysis
- Spondylolisthesis
- Scoliosis
- Lordotic deformities of the spine

• Spinal stenosis
• Failed previous spine surgery

TECHNICAL CHARACTERISTICS

Sphynx™ is made from titanium alloy that conforms to ASTM F136. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

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

The additions to the system include the following implants and instruments: 8.5mm and 9.0mm diameter screws and the associated instruments.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Type**
K922543	Z-Plate Anterior Fixation System	Sofamor Danek Mfg., Inc.	Primary
K962784	Ultium Spinal Plating System	Smith & Nephew Inc. Orthopaedic Division	Additional

Eden Spine Sphynx™ 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 bending, Static Torsion bending and and Dynamic Compression bending per ASTM F1717-14 were met. No clinical testing was performed.

CONCLUSION

The Sphynx™ has been tested per ASTM F1717 in static compression bending, dynamic compression bending and static torsion bending and were considered substantially equivalent to other legally marketed devices. The subject Sphynx™ 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 Sphynx™ is substantially equivalent to the predicate devices.