JAN 2 2 2014

5000 Plaza on the Lake, Suite 305
Austin, TX 78746
512-327-6400
800-640-6045 Fax
Dave Lamb dlamb@spine360.com

January 17, 2014

RE: 510(k)
Premarket Notification – Kestrel Posterior Cervical Fixation System K132122

Traditional 510(k) Summary

ESTABLISHMENT REGISTRATION NUMBER	3005841736
CONTACT PERSON	**Primary** Dave Lamb Quality and Regulatory Affairs Phone: 512-327-6400ext. 24 Fax: 800-640-6045
DATE PREPARED	June 30, 2013
CLASSIFICATION NAME	KWP 888.3050 - Spinal Interlaminal Fixation Orthosis
COMMON NAME	Posterior Occipital Cervico-thoracic Spinal System
TRADE NAME	Kestrel Posterior Cervical Fixation System
PREDICATE DEVICE	Anatomica Posterior Cervical Fixation System K061943
CLASS OF DEVICE	Class II

DEVICE DESCRIPTION

The proposed SPINE360 Kestrel system consists of screws, locking caps, rods, cross links, hooks, and instruments.

INTENDED USE

The Kestrel Posterior Cervical Fixation System is intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3). The system is intended for posterior, cervical, non-pedicle fixation, or for posterior, noncervical pedicle fixation for the following indications:

- Degenerative disc disease (DDD) 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
- Pseudoarthrosis
- Failed previous fusion

Occipital bone screws are limited to occipital fixation only. Pedicle bone screws are limited to placement in the upper thoracic spine (T1, T3) when anchoring the OCT construct only. Pedicle screws are not intended to be placed in the cervical spine. Hooks and wires (not pedicle screws) are used to achieve cervical fusion for the occipital/cervical loop

TECHNOLOGICAL CHARACTERISTICS

The Kestrel Posterior Cervical System implants are manufactured from titanium alloy, Ti – A16 – 4V (ISO 5832/3), which conforms to ASTM F136-02a (Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant Applications) material standards. The associated Class I instruments are made primarily of surgical grade stainless steel (ISO 7153/I).

SUBSTANTIAL EQUIVALENCE

	Anatomica	Kestrel
Indications for use	• Degenerative disc disease (DDD) • Spondylolisthesis • Trauma • Spinal stenosis, curvatures • Tumor • Pseudoarthrosis • Failed previous fusion	• Degenerative disc disease (DDD) • Spondylolisthesis • Trauma • Spinal stenosis, curvatures • Tumor • Pseudoarthrosis • Failed previous fusion
Material	Titanium 6Al 4V ELI	Titanium 6Al 4V ELI
Design features	Screws, connectors, hooks, wires, rods connected to stabilize the vertebrae during fusion	Screws, connectors, hooks, wires, rods connected to stabilize the vertebrae during fusion

PERFORMANCE TESTING TO ESTABLISH SUBSTANTIAL EQUIVALENCE

Mechanical Testing was performed in accordance with ASTM F2706-08 "Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model" including Static Compression Bending, Static Torsion, Dynamic Compression Bending, Dynamic TorsionThe results of the testing indicate that the Kestrel performed comparably or superior to the Anatomica predicate system.

CONCLUSIONS

The Kestrel Posterior Cervical System demonstrated substantial equivalence to the predicate Anatomica System (K061943).

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

January 22, 2014

Omni Surgical, LLC (dba. Spine 360)
Mr. David Lamb
5000 Plaza on the Lake, Suite 305
Austin, Texas 78746

Re: K132122
Trade/Device Name: Kestrel Posterior Cervical Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: December 11, 2013
Received: December 12, 2013

Dear Mr. Lamb:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5000 Plaza on the Lake, Suite 305
Austin, TX 78746
512-327-6400

RE: 510(k) K132122
Premarket Notification – Kestrel Posterior Cervical Fixation System

Indications for Use

The Kestrel Posterior Cervical Fixation System is intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3). The system is intended for posterior, cervical, non-pedicle fixation, or for posterior, noncervical pedicle fixation for the following indications:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132122