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

August 26, 2014

Next Orthosurgical, Incorporated
Mr. Huan Tran
Manager, Quality and Regulatory Affairs
3270 Corporate View, Suite A
Vista, California 92081

Re: K141291
Trade/Device Name: VertiForm Posterior Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH
Dated: July 23, 2014
Received: July 25, 2014

Dear Mr. Tran:

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,

Ronald P. Jean -S for

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

Enclosure

Indications for Use

510(k) Number: K141291

Device Name: VertiForm Posterior Fixation System

Indications For Use:

The VertiForm Posterior Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients for the following conditions: degenerative disc disease (DDD), DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies, spondylolisthesis, trauma (fracture or dislocation), spinal stenosis, curvatures (scoliosis, kyphosis, lordosis), tumor, pseudarthrosis (previous failed fusion). When used as posterior non-cervical pedicle screw fixation in pediatric patients, the Vertiform Posterior Fixation System is intended to treat adolescent idiopathic scoliosis. The device is intended to be used with autograft and or allograft to facilitate fusion.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
for the
VertiForm Posterior Fixation System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the VertiForm Posterior Fixation System

1. GENERAL INFORMATION

Date Prepared: May 19, 2014

Trade Name: VertiForm Posterior Fixation System

Common Name: Pedicle Screw

Classification Name: Pedicle Screw Spinal System

Class: III

Product Code: NKB, OSH, MNH, MNI

CFR section: 21 CFR section 888.3070

Device panel: Orthopedic

Legally Marketed Predicate Device: DePuy Moss Miami Spinal System Polyaxial Screws (K030383)

DePuy Expedium Spine System (K130877)

Biomet Spine Array Spinal System (K062685)

Medtronic CD Horizon Spinal System (K111457)

Submitter:

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2. DEVICE DESCRIPTION

The VertiForm Posterior Fixation System consists of pedicle screw assemblies, set screw, rod and crosslink. The pedicle screw assemblies consist of Polyaxial Pedicle Screw, Fixed Pedicle Screw, and Uniplanar Pedicle Screw and are in a variety of geometries and sizes to accommodate patient anatomy. They will be provided non-sterile and sterile. The VertiForm Posterior Fixation System is manufactured from Titanium alloy in accordance with ASTM F136, medical-grade commercially pure titanium per ASTM F67 and medical grade cobalt chrome per ASTM F-1537.

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The VertiForm Posterior Fixation System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The VertiForm Posterior Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients for the following conditions: degenerative disc disease (DDD), DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies, spondylolisthesis, trauma (fracture or dislocation), spinal stenosis, curvatures (scoliosis, kyphosis, lordosis), tumor, pseudarthrosis (previous failed fusion). When used as posterior non-cervical pedicle screw fixation in pediatric patients, the Vertiform Posterior Fixation System is intended to treat adolescent idiopathic scoliosis. The device is intended to be used with autograft and or allograft to facilitate fusion.

5. NON-CLINICAL TEST SUMMARY

Performance testing has been conducted for the subject devices in accordance with the following guidance documents:

- Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model, ASTM F1717
- Construct tests included:
  - Static Compression
  - Dynamic Compression
  - Static Torsion

The results of this testing indicate that the VertiForm Posterior Fixation System is equivalent to the predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed.

7. CONCLUSIONS NONCLINICAL AND CLINICAL

Next Orthosurgical considers the VertiForm Posterior Fixation System to be equivalent to the predicate devices listed above. This conclusion is based on the device's similarities in principles of operation, technology, materials and indications for use.