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

July 29, 2016

Next Orthosurgical
Ms. Ellen Yarnall
Director, Regulatory Affairs/Quality Assurance
3270 Corporate View, Suite A
Vista, California 92081

Re: K161499
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, MKB, MNI, MNH
Dated: July 1, 2016
Received: July 5, 2016

Dear Ms. Yarnall:

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 Parts 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" (21CFR 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,

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)*

K161499

Device Name
VertiForm Posterior Fixation System

Indications for Use *(Describe)*

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.

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)

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NEXT ORTHOSURGICAL

510(k) SUMMARY
VertiForm Posterior Fixation System

1. GENERAL INFORMATION

Submitted by:	Next Orthosurgical 3270 Corporate View Suite A Vista, CA 92081 (760) 295-3600 (Tel) (760) 295-3610 (Fax)
Contact:	Ellen Yarnall, Director of RA/QA
Proprietary Name:	VertiForm Posterior Fixation System
Classification Name:	Pedicle screw spinal system
Class:	III
Product Code:	NKB, OSH, MNI, MNH
CFR Section:	21 CFR 888.3070
Device Panel:	Orthopedic
Legally Marketed Predicate Device:	VertiForm Posterior Fixation System, K141291 (Primary)
Date Prepared:	July 1, 2016

2. DEVICE DESCRIPTION

The VertiForm Posterior Fixation System is a non-cervical spinal fixation system consisting of pedicle screws, set screws, rods and cross connectors. The pedicle screws are offered in a Polyaxial, Fixed or Uniplanar pedicle screw configuration and are available in a variety of geometries and sizes to accommodate patient anatomy. They are offered non-sterile and sterile. The VertiForm Posterior Fixation System is manufactured from titanium alloy (ASTM F136), medical-grade commercially pure titanium (ASTM F67) and medical-grade cobalt chrome (ASTM F1537). This Special 510(k) Premarket Notification seeks clearance to add variable cross connectors to the currently marketed VertiForm Posterior Fixation System.

3. 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.

4. TECHNOLOGICAL CHARACTERISTICS SUMMARY

The VertiForm Posterior Fixation System with Variable Cross Connectors has the same indications for use, materials and technological characteristics as the predicate device. Both systems include rod-to-rod connectors used to add stability to posterior non-cervical pedicle screw spinal systems. The subject device differs from the predicate in that the variable cross connectors allow angular and medial-lateral variability during implantation. Testing performed in accordance with guidance document; “Guidance for Industry and FDA Staff: Spinal Systems 510(k)s” resulted in a substantial equivalence determination.

5. NON-CLINCIAL TEST SUMMARY

Dynamic compression testing was performed in accordance with ASTM F1717, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model, 2004. Bacterial endotoxin testing was performed in accordance with ANSI/AAMI ST72. Testing results demonstrated that the VertiForm Posterior Fixation System with variable cross connectors performs comparable with the predicate device.

6. CONCLUSIONS

Based upon evidence accompanying this Special 510(k), and the fact that the Indications for Use, fundamental scientific technology, materials and performance characteristics are the same, it has been determined that the VertiForm Posterior Fixation System is substantially equivalent to the previously cleared device.