January 15, 2020

Next OrthoSurgical
Ms. Sartaj Kaur-Hurrle
Regulatory Affairs Manager
3270 Corporate View, Suite A
Vista, California 92081

Re: K190981
Trade/Device Name: NEX-D2 Posterior Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: December 20, 2019
Received: December 23, 2019

Dear Ms. Kaur-Hurrle:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

(Ronald Jean) Vacant
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190981

Device Name
NEX-D2 Posterior Fixation System

Indications for Use *(Describe)*

The NEX-D2 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 NEX-D2 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
NEX-D2 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 NEX-D2 Posterior Fixation System

1. GENERAL INFORMATION

Submitted by:
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Vista CA. 92081
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760-295-3610 (Fax)

Contact:
Sartaj Kaur-Hurrle, Regulatory Affairs Manager
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760-295-3600 (Tel)
760-295-3610 (Fax)
Email: skaur-hurrle@nextorthosurgical.com

Trade Name: NEX-D2 Posterior Fixation System

Common Name: Pedicle Screw System

Classification Name: Thoracolumbosacral Pedicle Screw System

Class: II

Product Code: NKB

CFR Section: 21 CFR 888.3070

Device panel: Orthopedic

Legally Marketed Predicate Device:
Next Orthosurgical, VertiForm Posterior Fixation System, K141291 (Primary Predicate)
Next Orthosurgical, VertiForm Posterior Fixation System, K161499
DePuy Moss Miami Spinal System Polyaxial Screws, K030383
Spinal Elements Mercury Spinal System, K172967

The predicates have not been subject to a design related recall.

Date Prepared: 1/10/2020

Purpose of Submission
The purpose of this submission is to gain clearance for additional components (line additions) to the NEX-D2 Posterior Fixation System, which is a non-cervical pedicle screw fixation system including hex-end/MIS titanium alloy and cobalt chrome alloy rods, additional large screw sizes, offset connectors, Rod to Rod Connectors and optional instruments.

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2. DEVICE DESCRIPTION

The Next Orthosurgical NEX-D2 Posterior Fixation System is a non-cervical pedicle screw system that consists of pedicle screws, rods, connectors, and set screws. All components are available in a variety of sizes to match patient anatomy. All components are manufactured from Ti-6Al-4V ELI per ASTM F136, commercially pure titanium per ASTM F67, and cobalt chrome alloy per ASTM F1537. These components are supplied either sterile or non-sterile.

3. INDICATIONS FOR USE

The NEX-D2 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 NEX-D2 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. SUBSTANTIAL EQUIVALENCE

The NEX-D2 Posterior Fixation System is substantially equivalent in indications for use, surgical technique, design features, materials used, mechanical performance, and instrumentation to the following predicate devices: Next Orthosurgical's VertiForm Posterior Fixation System (K141291, K161499), DePuy's Moss Miami Spinal System Polyaxial Screws (K030383) and Spinal Elements Mercury Spinal System (K172967).

5. NON-CLINICAL TEST SUMMARY

Mechanical testing was performed on the subject devices in accordance with relevant ASTM Standards listed below with each test mode. Mechanical tests included:

- Static Compression Bending per ASTM F1717
- Dynamic Compression Bending per ASTM F1717
- Static Torsion per ASTM F1717
- Axial Grip Strength per ASTM F1798
- Torsional Grip Strength per ASTM F1798
- Torsional Strength per ASTM F543
- Static Cantilever Bending Strength per ASTM F1798
- Dynamic Cantilever Bending Strength per ASTM F1798
- Static Polyaxial Head Pull off per ASTM F1798

Bacterial endotoxin testing was performed in accordance with ANSI/AAMI ST72.

Testing results demonstrate that the NEX-D2 Posterior Fixation System is substantially equivalent to the predicate devices. The subject devices met the pre-determined acceptance criteria.

6. CLINICAL TEST SUMMARY

No clinical studies were performed.

7. CONCLUSIONS NONCLINICAL AND CLINICAL

Next Orthosurgical considers the NEX-D2 Posterior Fixation System to be substantial 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.