October 29, 2019

Precision Spine
℅ Mr. J.D. Webb
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K192494
Trade/Device Name: NexGen Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 10, 2019
Received: September 11, 2019

Dear Mr. Webb:

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)*
K192494

Device Name
NexGen Anterior Cervical Plate System

Indications for Use *(Describe)*
The NexGen Anterior Cervical Plate System is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: degenerative disc disease (DDD) (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (including fractures or dislocations); spinal tumors; deformity (defined as kyphosis, lordosis, or scoliosis); spinal stenosis; pseudoarthrosis; and failed previous fusions.

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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*5*10(k) Summary:

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	September 10, 2019
Submitted By	Precision Spine 2050 Executive Drive Pearl, MS 39208
Primary Contact	J.D. Webb 4313 W. 3800 S West Haven, UT 84401 512-590-5810 e-mail: jdwebb@orthomedix.net
Secondary Contact	Michael C. Dawson Precision Spine 2050 Executive Drive Pearl, MS 39208 973-455-7150 ext. 128
Trade Name	NexGen Anterior Cervical Plate System
Common Name	Anterior Cervical Plate System
Classification Name	Spinal intervertebral body fixation orthosis
Class	II
Product Code	KWQ
CFR Section	21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate Device	Zion Anterior Cervical Plating System, Astura Medical (K160702)
Secondary Predicate Devices	C-Tek® MaxAn™Anterior Cervical Plate System, Biomet (K080646) CSLP Cervical Plate, Synthes (K000536) UNIPLATE, DePuy (K042544 / K082273 / K100070)
Reference Device	AccuFit™ Lateral Plate System, Precision Spine (K162211)
Device Description	The NexGen Anterior Cervical Plate System components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The NexGen Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates, screws (available in self-drilling or self-tapping configurations), and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.
Materials	Implants are made from Ti-6Al-4V ELI conforming to ASTM F136.
Intended Use	The NexGen Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion.
Substantial Equivalence Claimed to Predicate Devices	The NexGen Anterior Cervical Plate System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, and mechanical performance.
Indications for Use	The NexGen Anterior Cervical Plate System is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in

	patients with: degenerative disc disease (DDD) (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (including fractures or dislocations); spinal tumors; deformity (defined as kyphosis, lordosis, or scoliosis); spinal stenosis; pseudoarthrosis; and failed previous fusions.
Summary of the technological characteristics compared to predicate	When compared to the predicate devices, NexGen Anterior Cervical Plate System has the same intended use and similar technological characteristics, including: • Design • Materials of Construction • Function/Performance • Fundamental Scientific Technology • Principle of Operation
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic compression and torsion per ASTM F1717 The results of these evaluations show that the NexGen Anterior Cervical Plate System is as strong or stronger than the predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Precision Spine considers the NexGen Anterior Cervical Plate System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use