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

June 8, 2017

Choice Spine, LP
% Jim Banic
Senior Regulatory Affairs Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K170821
Trade/Device Name: ChoiceSpine™ Proliant® Posterior Pedicle Screw and Hook Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: March 17, 2017
Received: March 20, 2017

Dear Mr. Banic:

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,

Mark N. Melkerson -S

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)*
K170821

Device Name
Choice Spine™ Proliant® Posterior Pedicle Screw and Hook Fixation System

Indications for Use *(Describe)*

The Proliant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The Proliant system is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: (DDD) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis including severe spondylolisthesis (Grades 3 & 4) of L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; and failed previous fusion (pseudoarthrosis).

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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ChoiceSpine™ Proliant® Posterior Pedicle Screw and Hook Fixation System
Traditional 510(k)

510(k) Summary

Company: Choice Spine, LP
400 Erin Drive
Knoxville, TN 37919

Date: May 19, 2017

Contact Person: Jim Banic
Sr. Regulatory Affairs Specialist

Phone: (352) 327-4673
Fax: (352) 378-2617

Proprietary Name: ChoiceSpine™ Proliant® Posterior Pedicle Screw and Hook Fixation System

Common Name: Thoracolumbosacral Pedicle Screw System

Classification Name: 21 CFR 888.3070, Orthosis, Spinal Pedicle Fixation
21 CFR 888.3070, Orthosis, Spondyloisthesis Spinal Fixation
21 CFR 888.3050, Appliance, Fixation Interlaminal

Class II

Product Codes: NKB and KWP

Legally Marketed Devices to Which Substantial Equivalence Is Claimed:

Name	Manufacturer	510(k) Number
Proliant® Pedicle Screw System (Primary Predicate)	Exactech, Inc.	K102870
Expedium Spine System	DePuy Synthes	K110551

Device Description
The ChoiceSpine Proliant Posterior Pedicle Screw and Hook Fixation System is a top-loading spinal fixation system including screws, rods, and connectors for fixation to the thoracic, lumbar, and sacral spine. Components are manufactured from titanium alloy (Ti-6AI-4V ELI per ASTM F136) and Cobalt Chrome (Co-28Cr-6Mo per ASTM F1537) in various sizes. The system components are provided clean and non-sterile. The products must be steam sterilized by the hospital prior to use.

Indications for Use
The Proliant System is intended to provide immobilization and stabilization of spinal

segments in skeletally mature patients as an adjunct to fusion in the treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The Proliant system is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: (DDD) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis including severe spondylolisthesis (Grades 3 & 4) of L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; and failed previous fusion (pseudoarthrosis).

Submission Purpose
The purpose of this 510(k) submission is to all line extensions to the existing Proliant Pedicle Screw System, and to change the name from the Exactech Proliant Pedicle Screw System to the ChoiceSpine Proliant Pedicle Screw System

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use/Indications for Use.**
  Proliant Polyaxial Pedicle Screw and Hook Fixation System have similar indications for use and intended uses as its predicate device.

- **Materials**
  Proliant Posterior Pedicle Screw and Hook Fixation System and the predicate Proliant Polyaxial Pedicle Screw System are composed of titanium alloy (Ti-6Al-4V) per ASTM F136 and cobalt chrome per ASTM F1537, biocompatible materials conforming to a recognized industry standard for permanent implants.

- **Design Features**
  Proliant Posterior Pedicle Screw and Hook Fixation System and the predicate Proliant Pedicle Screw System have similar design features.

- **Dimensions**
  Proliant Posterior Pedicle Screw and Hook Fixation System and the predicate Proliant System are dimensionally comparable.

- **Packaging and Sterilization**
  Proliant Posterior Pedicle Screw and Hook Fixation System and the predicate Proliant Pedicle Screw System are provided non-sterile, for single use only, and will be steam sterilized by the hospital prior to use in the operating room using the same sterilization method.

- **Device Shelf Life**

Neither Proliant Posterior Pedicle Screw and Hook Fixation System and the predicate Proliant Pedicle Screw System have shelf life expiration dating.

- **Performance specifications**
  The proposed Proliant System line extensions have been tested in the following test modes.
  - Static axial compression bending per ASTM F1717-14
  - Static torsion per ASTM F1717-14
  - Dynamic axial bending per ASTM F1717-14

The results of this non-clinical testing show the strength of the Proliant Posterior Pedicle Screw and Hook Fixation System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

Substantial Equivalence Conclusion

Results from mechanical tests and biomechanical assessment demonstrate the proposed Proliant Posterior Pedicle Screw and Hook System is substantially equivalent to the predicate Proliant Pedicle Screw System.