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 3, 2016

Choice Spine LP
Ms. Kim Finch
Manager of Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

Re: K160775
Trade/Device Name: Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: March 18, 2016
Received: March 21, 2016

Dear Ms. Finch:
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 yours,

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)*
K160775

Device Name
Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems

Indications for Use *(Describe)*
The Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

When used in a posterior percutaneous approach with MIS instrumentation, the Thunderbolt™ System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used for hook fixation, The Lancer™ Open Pedicle Screw System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous 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.

510(k) Summary

Date Prepared:	May 27, 2016
Sponsor:	Choice Spine, LP 400 Erin Drive Knoxville, TN 37919
Phone:	865-243-3969
Fax:	865-246-3334
Contact Person:	Kim Finch, Manager of Regulatory Affairs
Proposed Proprietary Trade Name:	Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems
Product Class:	Class III
Classification Name:	888.3060 Spinal Interlaminal Fixation Orthosis 888.3070 - Pedicle Screw Spinal System
Device Product Code:	NKB, MNH, MNI, KWP
Purpose of Submission:	The purpose of this submission is to gain clearance for additional hooks and the additional KWP product code indication to the already cleared Thunderbolt™ and Lancer™ Pedicle screw System.
Device Description:	The Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems includes components made of implant grade titanium alloy (Ti6Al4V ELI; ASTM F136-02A), cobalt chrome alloy (Co-28Cr-6Mo per ASTM F1537, and instrumentation made of PEEK (ASTM F2826) and stainless steel per ASTM F899. These components are available in various designs and sizes that allow the surgeon to build an implant construct suited to a patient's anatomical and physiological requirements. The components include: pedicle (polyaxial) screws, set screws, rods, hooks, instruments, and sterilizer trays. Additionally, cross connector components are available with the Lancer™ Open Pedicle system.

Indications: The Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

When used in a posterior percutaneous approach with MIS instrumentation, the Thunderbolt™ System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used for hook fixation, The Lancer™ Open Pedicle Screw System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease(DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Predicate Devices: (Primary) Alphatec Zodiac (K033090)
Thunderbolt and Lancer™ Pedicle Spinal System (K132049)
Globus Revere (K061202)

Performance Standards: Torsional Grip and Axial Grip per ASTM F1798

Conclusion: Choice Spine concludes that the Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw System is equivalent to the primary predicate, Alphatec - Zodiac (K033090) as well as the additional predicates Choice Spine Thunderbolt™ and Lancer™ (K132049), and Globus Revere (K061202) systems.
Equivalence is based on the similarities in the indications for/intended use, design, product offering, materials used and levels of attachment when compared to the predicates.