



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

April 26, 2017

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

Re: K170942

Trade/Device Name: The Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle
Screw Systems

Regulation Number: 21 CFR 888.3070

Regulation Name: Thoracolumbosacral pedicle screw system

Regulatory Class: Class II

Product Code: NKB, KWP

Dated: March 24, 2017

Received: March 30, 2017

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 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

Indications for Use

510(k) Number (if known)

K170942

Device Name

The 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™ Minimally Invasive 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Date Prepared: April 19, 2017

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: The Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems

Product Class: Class II

Classification Name: 888.3070 – Thoracolumbosacral Pedicle Screw System

Device Product Code: NKB, KWP

Purpose of Submission: The purpose of this submission is to gain clearance for additional size screws to the already cleared Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems.

Device Description: The Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems include implant components made of implant grade titanium alloy (Ti-6Al-4V ELI; ASTM F136) and cobalt chrome alloy (Co-28Cr-6Mo; ASTM F1537). The systems also include instruments made of PEEK (ASTM F2826), Tantalum (ASTM F560), stainless steel (ASTM F899/A564) and aluminum (ASTM B221). 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: polyaxial pedicle screws, set screws, rods, instruments and sterilizer trays. The Lancer™ Open Pedicle Screw System also includes cross connector and hook components.

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™ Minimally Invasive 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: Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw Systems K132049 and K160775 (Primary Predicate).

Non-Clinical Evaluations: The subject implants were demonstrated to not represent a new worst case through engineering analysis.

Conclusion: Choice Spine concludes that the Thunderbolt™ Minimally Invasive and Lancer™ Pedicle Screw System is equivalent to Thunderbolt™ Minimally Invasive and Lancer™ Open Pedicle Screw System K132049 and K160775. 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.