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

May 19, 2016

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

Re: K153107
Trade/Device Name: Choice Spine Lumbar Spacer System (Sabre™, Shark™, Hornet™, Harpoon™), Choice Spine VEO™ Lateral Access & Interbody Fusion System, Choice Spine Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: April 22, 2016
Received: April 25, 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)*
K153107

Device Name
Choice Spine Lumbar Spacer System (Sabre™, Shark™, Hornet™, Harpoon™)
Choice Spine VEO™ Lateral Access & Interbody Fusion System
Choice Spine Interbody Fusion System

Indications for Use *(Describe)*

Choice Spine Lumbar Spacer System (Sabre, Shark, Hornet, Harpoon):
The Choice Spine Lumbar Spacer System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1 in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.
When used as a vertebral body replacement device, the Choice Spine Intervertebral Body Device is intended for use in the thoracic and lumbar spine, from T1 to L5, for the replacement of a collapsed or unstable vertebral body resulting from a tumor or traumatic injury. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Choice Spine VEO™ Lateral Access & Interbody Fusion System:
The Choice Spine VEO™ Lateral Access & Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Choice Spine VEO™ Lateral Access & Interbody Fusion System is designed to be used with autogenous graft and supplemental spinal fixation that is cleared for use in the lumbar spine.

Choice Spine Interbody Fusion System:
The Choice Spine Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Choice Spine Interbody Fusion System is designed to be used with autogenous bone graft and a supplemental spinal fixation system that is cleared for use in the lumbar spine.

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

Date	May 17, 2016
Sponsor:	Choice Spine, LP 400 Erin Drive Knoxville, TN 37919
Phone:	865-246-3333
Fax:	865-246-3334
Contact Person:	Kim Finch, Manager of Regulatory Affairs
Proposed Proprietary Trade Name:	Choice Spine Lumbar Spacer System (Sabre™, Shark™, Hornet™, Harpoon™) Choice Spine VEO™ Lateral Access & Interbody Fusion System Choice Spine Interbody Fusion System
Product Class:	Class II
Classification Name:	Choice Spine Lumbar Spacer System (Sabre™, Shark™, Hornet™, Harpoon™): • 888.3080- Spinal Intervertebral Body Fusion Device • 888.3060- Spinal Intervertebral Body Fixation Orthosis Choice Spine VEO™ Lateral Access & Interbody Fusion System: • 888.3080- Spinal Intervertebral Body Fusion Device Choice Spine Interbody Fusion System: • 888.3080- Spinal Intervertebral Body Fusion Device
Device Product Code:	Choice Spine Lumbar Spacer System (Sabre™, Shark™, Hornet™, Harpoon™): • MAX, MQP Choice Spine VEO™ Lateral Access & Interbody Fusion System: • MAX Choice Spine Interbody Fusion System: • MAX
Purpose of Submission:	The purpose of this submission is to gain clearance for additional devices manufactured from titanium-alloy. The previously cleared system are Choice Spine Lumbar Spacer System, K140142 and K073669, Choice Spine VEO™ Lateral Access & Interbody Fusion System (Formerly TranS1 Lateral Interbody Fusion System) K100210 and K123997, and Choice Spine Interbody Fusion System (Formerly TranS1 Interbody Fusion System) K120991. The latter two TranS1 systems were acquired by Choice Spine in 2015.

Device Description:

This submission includes three lumbar implant families. The device description for each family is listed below.

Choice Spine Lumbar Spacer System (Sabre, Shark, Hornet, Harpoon):

The Choice Spine Lumbar Spacer System consists of interbody fusion devices (specifically, SABRE, SHARK™, HORNET™ & HARPOON™ Lumbar Spacers) comprised of polyetheretherketone (PEEK - Optima®) with tantalum markers (ASTM F2026 and ASTM F560) or Ti-6Al-4V ELI (ASTM F136). The spacers have a basic rectangular shape, a hollow center for placement of bone graft and a smooth bullet shaped anterior surface. They are available in an assortment of height, length and anteroposterior angulation combinations to accommodate many different anatomic requirements. These implants are delivered via a posterior or transforaminal approach.

Choice Spine VEO™ Lateral Access & Interbody Fusion System:

The Choice Spine VEO™ Lateral Access & Interbody Fusion System is a multi-component system including instrumentation made of stainless steel, Aluminum, and Radel R and implants made of tantalum (ASTM F560) and PEEK Optima® (ASTM F2026) or Ti-6Al-4V ELI (ASTM F136). The implants are delivered via lateral approach.

Choice Spine Interbody Fusion System:

The Choice Spine Interbody Fusion System is a family of implants intended to aid in spinal fixation of the lumbar spine. This system includes implants made of Zeniva ZA-500 PEEK (ASTM F2026) with Tantalum markers (ASTM F560) or Ti-6Al-4V ELI (ASTM F136), which are delivered via anterior or anterolateral approach.

Intended Use:

Choice Spine Lumbar Spacer System (Sabre, Shark, Hornet, Harpoon):

The Choice Spine Lumbar Spacer System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1 in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

When used as a vertebral body replacement device, the Choice Spine Intervertebral Body Device is intended for use in the thoracic and lumbar spine, from T1 to L5, for the replacement of a collapsed or unstable vertebral body resulting from a tumor or traumatic injury. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Choice Spine VEO™ Lateral Access & Interbody Fusion System:

The Choice Spine VEO™ Lateral Access & Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with

degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Choice Spine VEO™ Lateral Access & Interbody Fusion System is designed to be used with autogenous graft and supplemental spinal fixation that is cleared for use in the lumbar spine.

Choice Spine Interbody Fusion System:

The Choice Spine Interbody Fusion System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Choice Spine Interbody Fusion System is designed to be used with autogenous bone graft and a supplemental spinal fixation system that is cleared for use in the lumbar spine.

Comparison of Technological Characteristics:

The implants included in this submission are equivalent to the primary predicate Alphatec Battalion Universal Spacer System (K143740), and additional predicates are Choice Spine Lumbar Spacer System (K140142 and K073669), Choice Spine Interbody Fusion System (K120991), and the Choice Spine VEO™ Lateral Access & Interbody Fusion Device System (K100210 and K123997).

Non-Clinical Testing:

The worst case design for each family does not change if the implant was manufactured from Titanium instead of PEEK. Therefore, no new non-clinical testing is needed.

Conclusion:

The subject implants are substantially equivalent in intended use, anatomic location, indications, method of stabilization, and material of manufacture.