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

November 23, 2016

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

Re: K162103
Trade/Device Name: Choice Spine Lumbar Spacer System (Sabre™, Shark™, Hornet™, Harpoon™), Choice Spine Interbody Fusion System (Harrier™), Choice Spine Vertebral Body Replacement System (Hawkeye™)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: October 25, 2016
Received: October 26, 2016

Dear Kim 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 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)*
K162103

Device Name
Choice Spine Lumbar Spacer System (Sabre™, Shark™, Hornet™, Harpoon™)
Choice Spine Interbody Fusion System (Harrier™)
Choice Spine Vertebral Body Replacement System (Hawkeye™)

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 autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft 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 autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

Choice Spine Interbody Fusion System (Harrier™):

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 and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and a supplemental spinal fixation system that is cleared for use in the lumbar spine.

Choice Spine Vertebral Body Replacement System (Hawkeye™):

The Choice Spine Vertebral Body Replacement (VBR) System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The Choice Spine Vertebral Replacement (VBR) System is intended for use with supplemental fixation and is to be used with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate 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.

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8. 510(k) Summary

Date	November 7, 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 Interbody Fusion System (Harrier™) Choice Spine Vertebral Body Replacement System (Hawkeye™)
Product Class:	Class II
Classification Name:	Choice Spine Lumbar Spacer System (Sabre™, Shark™, Hornet™, Harpoon™): • 888.3080- Intervertebral Body Fusion Device • 888.3060- Spinal Intervertebral Body Fixation Orthosis Choice Spine Interbody Fusion System (Harrier™): • 888.3080- Intervertebral Body Fusion Device Choice Spine Vertebral Body Replacement (Hawkeye™): • 888.3060- Spinal Intervertebral Body Fixation Orthosis
Device Product Code:	Choice Spine Lumbar Spacer System (Sabre™, Shark™, Hornet™, Harpoon™): • MAX, MQP Choice Spine Interbody Fusion System (Harrier™): • MAX Choice Spine Vertebral Body Replacement System (Hawkeye™): • MQP
Purpose of Submission:	The purpose of this submission is to gain clearance for additional sizes of the Choice Spine Lumbar Spacer System and Choice Spine Interbody Fusion System in both PEEK and Titanium and to gain clearance for the Choice Spine Vertebral Body Replacement System implant family in Titanium. The Choice Spine Lumbar Spacer System has been cleared by the FDA in PEEK (K140142, K073669) and Titanium (K153107). The Choice Spine Interbody Fusion System (Formerly TranS1 Interbody Fusion System) has been cleared in PEEK (K120991) and Titanium (K153107). The Choice Spine Vertebral Body Replacement System has been

cleared in PEEK (K120570). The indications for these systems have been expanded to include autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

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 autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft 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 autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion.

Choice Spine Interbody Fusion System (Harrier™):

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 and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and a supplemental spinal spinal fixation system that is cleared for use in the lumbar spine.

Choice Spine Vertebral Body Replacement System (Hawkeye™):

The Choice Spine Vertebral Body Replacement (VBR) System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The Choice Spine Vertebral Replacement (VBR) System is intended for use with supplemental fixation and is to be used with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion

Materials:

The implant components are available in two material varieties, polyetheretherketone (PEEK-OPTIMA® LT1, Invibio® or Zeniva® PEEK, Solvay) as described by ASTM F2026 with integral radiopaque markers manufactured from tantalum as described by ASTM F560. The second implant variety is Titanium alloy (Ti-6Al-4V ELI) which conforms to ASTM F136. All chosen materials are commonly used in medical devices. The implants will be provided non-sterile, but will be steam sterilized before use.

Substantial Equivalence:

The subject devices in this submission are equivalent to the following predicates in intended use, anatomic location, indications, and method of stabilization and the material of manufacture. Choice Spine Lumbar Spacer System (K140142) is the primary predicate. Additional predicates are the Choice Spine Intervertebral Body Device (K153107), The Choice Spine Interbody Fusion System (K120991), and the Avenue® L Lateral Lumbar Cage, Avenue® T TLIF Cage System, ROI-A® ALIF Cage System, ROI-T® Implant System (K153495).

Titanium was chosen as a material option due to its known biocompatibility and its widespread use in spinal and orthopedic implants. Because the designs of the implants are similar between material types (PEEK or Titanitum Alloy) and have been previously cleared, the implants made out of Titanium will be stronger than the implants manufactured from PEEK due to the material properties of Titanium. The ability for an implant to stabilize for fusion is dependent on the geometry of the implant which includes tooth design, surface area, and footprint. The additional sizes in this submission do not introduce a new worst case. 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.