February 22, 2019

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

Re: K183588
Trade/Device Name: Choice Spine HAWKEYE™ Vertebral Body Replacement (VBR) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: MQP, PLR
Dated: January 25, 2019
Received: January 28, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

For 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)*
K183588

Device Name
Choice Spine HAWKEYE™ Vertebral Body Replacement (VBR) System

Indications for Use *(Describe)*
The Choice Spine HAWKEYE™ Vertebral Body Replacement (VBR) Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5). Hawkeye (VBR) Spacers are also intended for use in the cervical spine (C2-T1).
When used in the cervical spine (C2-T1), the HAWKEYE™ VBR devices are intended for use in the skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.
When used in the thoracolumbar spine (T1-L5), the HAWKEYE ™ VBR Spacers are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.
The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.
These devices are intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e.,posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

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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7. 510(k) Summary

Date:	February 13, 2019
Sponsor:	ChoiceSpine, LP 400 Erin Drive Knoxville, TN 37919
Phone:	865-246-3333
Fax:	865-246-3334
Contact Person:	Kim Finch, Director of Regulatory Affairs
Proposed Proprietary Trade Name:	Choice Spine HAWKEYE™ Vertebral Body Replacement (VBR) System
Product Class:	Class II
Classification Name:	888.3060 - Spinal Intervertebral Body Fixation Orthosis
Device Product Code:	MQP, PLR
Purpose of Submission:	The purpose of this submission is to gain clearance for cervical indications of the ChoiceSpine HAWKEYE™ Vertebral Body Replacement (VBR) System for use in the thoracolumbar spine (T1-L5) and cervical spine (C2-T1) in Titanium (K162103), and additive manufactured titanium (K171686).
Device Description:	The ChoiceSpine HAWKEYE™ Vertebral Body Replacement (VBR) System is composed of implant components which have a basic oval/trapezoidal shape with a hollow center for placement of bone graft. The superior and inferior surfaces have ridges, or "teeth" for resisting migration. The replacement implants, "spacers", are available in an assortment of heights and in multiple angles of lordosis to accommodate different anatomic requirements.
Intended Use:	The ChoiceSpine HAWKEYE™ Vertebral Body Replacement (VBR) System Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5). Hawkeye (VBR) Spacers are also intended for use in the cervical spine (C2-T1). When used in the cervical spine (C2-T1), the HAWKEYE™ VBR devices are intended for use in the skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These spacers are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion. When used in the thoracolumbar spine (T1-L5), the HAWKEYE ™ VBR Spacers are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

	The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion. These devices are intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e., posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.
Materials:	The implant components are available in Titanium alloy (Ti-6Al-4V ELI) which conforms to ASTM F136 or ASTM F3001. 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 ChoiceSpine HAWKEYE™ Vertebral Body Replacement (VBR) System with cervical indication is equivalent to the primary predicate (K171686) and additional predicates Globus Medical Fortify® Corpectomy Spacers (K162315). The ChoiceSpine Vertebral Body Replacement (VBR) System has been cleared by the FDA in Titanium (K162103). The predicate devices are equivalent in principle of operation, indications for use, material, biocompatibility, sterilization method, stabilization method, anatomic location and approach, product code and classification, and footprints (length & width).
Performance Data:	Mechanical testing (static and dynamic compression and torsion, subsidence and expulsion) was conducted in accordance with the Guidance for Industry & FDA staff Class II Special Controls Guidance Document, Intervertebral Fusion Device per ASTM F2077, and ASTM F2267 and provided in the predicate submissions K171686 to demonstrate substantial equivalence.
Clinical Literature:	A clinical literature review was performed to support the use of subject devices in the cervical spine. The risk of cervical use was identified and mitigated through design and surgical technique. Based on clinical literature, it was determined that the safety profile of subject devices is equivalent to that of the predicate devices.
Technological Characteristics:	The ChoiceSpine HAWKEYE™ VBR System implants have the same technological characteristics as the predicate devices through design, intended use, materials, function, and range of sizes.
Conclusion:	The ChoiceSpine HAWKEYE™ VBR System have the same intended use, same technological characteristics, design, materials, and same principles of operation as the predicates.