September 15, 2017

Choice Spine
Kim Finch
Manager Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37924

Re: K171686
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
Dated: August 16, 2017
Received: August 17, 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 (DICE) 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 (DICE) 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

The Choice Spine Hawkeye™ 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 Hawkeye™ Vertebral Body 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.

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

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510(k) Summary

Date: September 13, 2017
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 Hawkeye™ Vertebral Body Replacement (VBR) System
Product Class: Class II
Classification Name: 888.3060 - Spinal Intervertebral Body Fixation Orthosis

Device Description: The Choice Spine 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. This system includes implants made of PEEK (ASTM F2026) with Tantalum markers (ASTM F560) or Ti-6Al-4V ELI (ASTM F136 or ASTM F3001).

Intended Use: The Choice Spine Hawkeye™ 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 Hawkeye™ Vertebral Body 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®) per ASTM F2026 with integral radiopaque markers manufactured from tantalum per ASTM F560, and 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 current subject devices in this submission are equivalent to the Choice Spine Vertebra Body Replacement (VBR) System K120570 (primary) and K162103, Choice Spine Lumbar Spacer System K153107 as additional predicates. The predicate devices are equivalent in principle of operation, indications for use, material, biocompatibility, manufacturing methods/post processing steps, sterilization method, stabilization method, anatomic location and approach, product code and classification, and footprints (length & width). The additional taller height sizes in this submission, along with the new additive manufacturing method per ASTM F3001 and slight design change of being more trapezoidal and having window cutouts, introduce a new worst case for design. The performance data is substantially equivalent when compared to the primary predicate.

Conclusion: The additional implants proposed in this submission are identical in: Principle of Operation, Indications for Use, Biocompatibility, Sterilization and Stabilization Method, Anatomic Location and Approach, Intended Use, Product Code and Classification, and Footprints (Length & Width) to the previously cleared implants in this family.

The addition of the taller heights (51-60mm) represents a new worst case implant design along with a change in manufacturing method. Therefore, the worst-case size of the additional implants proposed in this submission was subjected to mechanical testing, which is discussed in detail in section 22, and results (along with the comparison in section 14.1) showed that the subject device is substantially equivalent to the predicates listed.

Non-clinical Testing: The non-clinical testing performed was Static Axial Compression, Static Torsion, Dynamic Torsion, Dynamic Compression per ASTM F2077, Subsidence per ASTM F2267, and Expulsion testing.