September 14, 2023

ChoiceSpine, LLC
Kim Finch
Director of Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

Re: K223869
Trade/Device Name: ChoiceSpine Blackhawk Ti Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: August 17, 2023
Received: August 18, 2023

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223869

Device Name
ChoiceSpine Blackhawk Ti Cervical Spacer System

Indications for Use *(Describe)*
The Blackhawk Ti Cervical Spacer System is a stand-alone anterior cervical interbody fusion device indicated for use in a skeletally mature patient with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Blackhawk Ti Cervical Spacer System is to be used with autogenous bone and/or allogenic 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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510(k) Summary

Date:	September 11, 2023
Sponsor:	ChoiceSpine, LLC 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:	ChoiceSpine Blackhawk™ Ti Cervical Spacer System
Product Class:	Class II
Classification Name:	ChoiceSpine Blackhawk™ Ti Cervical Spacer System 888.3080 - Intervertebral Fusion Device with Integrated Fixation, Cervical
Device Product Code:	ChoiceSpine Blackhawk™ Ti Cervical Spacer System OVE

Purpose of Submission: The purpose is to modify our existing ChoiceSpine Blackhawk™ Cervical Spacer System (K203311). Modifying the intended use to include stand-alone indication and updating the labeling.

Device Description: The Blackhawk™ Ti Cervical Spacer System is a stand-alone anterior cervical interbody device consisting of a titanium alloy (Ti-6Al-4V ELI) implant cage per ASTM F3001, nitinol internal locking components per ASTM F2063, two internal titanium alloy (Ti-6Al- 4V ELI) anchors per ASTM F136, and a titanium alloy (Ti-6Al-4V ELI) locking cam per ASTM F136. They are intended for use as interbody fusion devices and are offered in a variety of heights, footprints, and lordotic angles to accommodate varying anatomical conditions. The device features a chamber intended to be filled with autogenous bone and/or allogenic bone graft material. The Blackhawk™ Ti Cervical Spacer System is used with two internal bladed anchors that lock on deployment and provide additional fixation.

The integrated fixation anchors may not provide adequate stability for all situations. The surgeon should consider the appropriate fixation required for each patient and determine if additional supplemental fixation (e.g., an anterior plate, posterior pedicle screws) may be needed.

Indications for Use: The Blackhawk™ Ti Cervical Spacer System is a stand-alone anterior cervical interbody fusion device indicated for use in a skeletally mature patient with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the

disc conformed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Blackhawk™ Ti Cervical Spacer System is to be used with autogenous bone and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, to facilitate fusion.

Materials:	The Blackhawk™ Ti Cervical Spacer System implants are composed of a titanium alloy (Ti-6Al- 4V ELI per ASTM F3001, Class C) implant spacer, nitinol (per ASTM F2063) internal locking clips, titanium alloy (Ti-6Al-4V ELI per ASTM F136) anchors, and a titanium alloy (Ti-6Al-4V ELI per ASTM F136) locking cam. The implant body, cam, and anchors are composed of Titanium alloy Ti-6Al-4V per ASTM F136/F3001, which has a long history of safe and effective use in orthopedic implants. The locking clips are composed of nitinol per ASTM F2063, which has a long history of safe and effective use in orthopedic implants. The Blackhawk™ Ti Cervical Spacer System implants will be provided sterile. Instruments will be provided non-sterile but will be steam sterilized before use. The instrumentation is made from 17-4 Stainless Steel (ASTM F899/A693), 465 Stainless Steel (ASTM F899), titanium alloy (Ti-6Al-4V ELI Grade 5 per ASTM F136), and polyphenylsulfone (Radel R5000 Series).
Predicate Devices:	**Primary Predicate:** ChoiceSpine Tomcat™ Cervical Spacer System (K170953) **Additional Predicates:** ChoiceSpine Blackhawk™ Cervical Spacer System (K203311)
Non-clinical Testing:	Static subsidence per ASTM F2267-04 Expulsion (standard N/A) Dynamic axial compression per ASTM F2077-18 Dynamic compression-shear per ASTM F2077-18 Dynamic torsion per ASTM F2077-18 ROM Cadaveric testing of the Tomcat & Blackhawk Ti Implants
Technological Characteristics:	The implants proposed in this submission are similar to the predicate devices in the principle of operation, indications for use, stabilization method, anatomic location and approach, product code and classification, and biocompatibility. The subject device has similar geometry and identical footprints as the primary predicate (Tomcat Cervical Spacer System). The subject device's spacer component is made out of titanium alloy whereas the primary predicate's spacer component is made out of PEEK. The anchor components of the subject devices are made out of the same titanium alloy. The primary predicate Tomcat is secured by two screws with an internal locking mechanism, whereas the Blackhawk Ti has two bladed anchors secured with a titanium cam lock and locking clips that are deployed in an equivalent fashion. The Blackhawk Ti Cervical Spacer is a 3D printed device and manufacturing process remains unchanged since initially cleared under K203311.

Substantial Equivalence Conclusion:	Cadaveric range of motion testing was performed comparing the design to a previously cleared standalone device. The results demonstrate the subject device is substantially equivalent to the predicate devices in safety, effectiveness, and performance. While the designs are different, the mechanical strength and stabilization performance are equivalent as demonstrated through ASTM F2077 and ASTM F2267 testing and cadaveric testing.
	The subject device is provided sterile and are processed at the same supplier as previously cleared Blackhawk Ti K203311. ChoiceSpine's sterilization process has been validated through gamma validation and distribution testing and the results demonstrate that the predetermined acceptance criteria were met. The minimum radiation dose of 25kGy was sufficient to meet a sterilization assurance level (SAL) of 10^{-6} and the package system remained intact while also maintaining the hermetic barrier.