



May 10, 2021

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

Re: K203311

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: April 20, 2021
Received: April 22, 2021

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/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,

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

Indications for Use

510(k) Number (if known)

K203311

Device Name

Blackhawk™ Ti Cervical Spacer System

Indications for Use (Describe)

The Blackhawk™ Ti Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (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 composed of cancellous and /or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach.

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: March 19, 2021
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 of this submission is to gain clearance for the new ChoiceSpine Blackhawk™ Ti Cervical Spacer System, which consists of implant spacers made of Ti-6Al-4V ELI per ASTM F3001 (Class C). The subject implant devices & instrumentation will be used with additional previously cleared instrumentation. The subject implant introduces material, design, and manufacturing method changes to the previously cleared ChoiceSpine Blackhawk Cervical Spacer System.

Device Description: The Blackhawk™ Ti Cervical Spacer System is an anterior cervical interbody device consisting of a titanium alloy (Ti-4Al-6V 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 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 anchors that lock on deployment and provide additional fixation.

Indications for Use: The Blackhawk™ Ti Cervical Spacer System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease at one disc level from C2-T1. Degenerative Disc Disease (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 composed of cancellous and /or corticocancellous bone graft, and supplemental fixation (i.e., an anterior cervical plate), and is implanted via an open, anterior approach.

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 either ASTM F136 or ASTM 3001, 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 Blackhawk™ Cervical Spacer System (K191621 and K171489)
Additional Predicates:
ChoiceSpine Tomcat™ Cervical Spacer System (K170953)
Exactech Acapella One Cervical Spacer System (K132582)
ChoiceSpine Tiger Shark C™ Cervical Spacer System (K201643)

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

Substantial Equivalence Conclusion:

The implants proposed in this submission are similar to the predicate devices in 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 (Blackhawk 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 and primary predicate devices are made out of the same titanium alloy material and are deployed in an equivalent fashion. The locking mechanism of the subject device utilizes a new cam component whereas the primary predicate utilized pins and clips. While the designs are different, the mechanical strength and stabilization performance are equivalent as demonstrated through ASTM F2077 and ASTM F2267 testing.

The subject device's spacer component and predicate Tiger Shark Cervical Spacer (K201643) are both manufactured at the same supplier using identical additive and traditional manufacturing processes.

The subject device and predicates are all provided sterile and are processed at the same supplier. 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.

The worst-case device among the proposed system was identified and mechanical testing was conducted to prove the new design is substantially equivalent to the predicates. Therefore, after including all other similarities and performing mechanical testing, the proposed device is shown to be equivalent to the predicate devices in safety, effectiveness, and performance.