December 22, 2020

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

Re: K201643
Trade/Device Name: ChoiceSpine Tiger Shark™ Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 2, 2020
Received: December 3, 2020

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 L. 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K201643

Device Name
ChoiceSpine Tiger Shark™ Cervical Spacer System

Indications for Use *(Describe)*
The Tiger Shark Cervical Spacer System is intended for anterior cervical spine intervertebral body fusion at one level from the C2-C3 disc space to the C7-T1 disc for the treatment of degenerative disc disease (DDD) in skeletally mature patients who have had six (6) weeks of non-operative treatment. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The TiGER SHARK Cervical Spacer System is to be used with supplemental fixation and with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft to facilitate fusion.

☒ 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	June 15, 2020
Sponsor	ChoiceSpine, LLC 400 Erin Drive Knoxville, TN 37919
Phone	865-243-3969
Fax	865-246-3334
Contact Person	Kim Finch, Director of Regulatory Affairs
Proposed Proprietary Trade Name	ChoiceSpine Tiger Shark™ Cervical Spacer System
Product Class	Class II
Classification Name	ChoiceSpine Tiger Shark™ Cervical Spacer System • 888.3080 - Spinal Intervertebral Body Fusion Device
Device Product Code	ChoiceSpine Tiger Shark™ Cervical Spacer System: • ODP
Purpose of Submission	The purpose of this submission is to gain clearance for adding an additional titanium implant footprint in 18x15mm size and instruments to the ChoiceSpine Tiger Shark™ Cervical Spacer System. This device has been previously submitted as ChoiceSpine Stealth™ Cervical Spacer System, (K183397) and has undergone additional technical upgrades per ChoiceSpine design control including porous titanium regions and a slight change in profile within the scope of K183397. It has since been trade marked as Tiger Shark™ Cervical Spacer System.
Device Description	The ChoiceSpine Tiger Shark™ Cervical Spacer System consists of intervertebral body fusion devices comprised of titanium alloy (Ti-6AI-4V ELI per ASTM F3001, Class C). The spacers have a basic oval shape that coincides with the shape of vertebral bodies and a hollow center for placement of bone graft. They are available in an assortment of heights and in multiple angles of lordosis to accommodate different anatomic requirements. The devices are manufactured using the Electron Beam Melting (EBM) additive manufacturing method.
Indications for Use	The Tiger Shark™ Cervical Spacer System is intended for anterior cervical spine intervertebral body fusion at one level from the C2-C3 disc space to the C7-T1 disc for the treatment of degenerative disc disease (DDD) in skeletally mature patients who have had six (6) weeks of non-operative treatment. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic

studies. The Tiger Shark™ Cervical Spacer System is to be used with supplemental fixation and with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft to facilitate fusion.

Materials	The implants are made from either titanium alloy (Ti-6Al-4V ELI per ASTM F3001, Class C). Implants will be provided sterile. Instruments will be provided non-sterile but will be steam sterilized before use. The instrumentation is made from 455/465 SS per ASTM A564, 17-4 SS per ASTM F899 and 6061 T6 Aluminum per ASTM B209/B221.
Predicate Device	**Primary predicate**: Genesys Spine Apache Cervical Interbody Fusion System (K150812) **Additional Predicate**: ChoiceSpine Tiger Shark Cervical Spacer System (K183397)
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 indications for use were compared; the differences include the primary predicate is cleared for use with autograft while the subject device and additional predicate are intended to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. The addition of the allogenic bone graft material does not alter the device intended use. The additional footprint spacer is within the size range of the primary predicate, Genesys Spine Apache Cervical Interbody Fusion System (K150812). The larger footprint does not make a new worse case when compared to the worse case cleared in the additional predicate, ChoiceSpine Tiger Shark Cervical Spacer System (K183397). The subject device and additional predicate are both provided sterile while the primary predicate is provided non-sterile. 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.