September 13, 2022

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

Re: K220953
Trade/Device Name: ChoiceSpine TigerShark™ M, Modular Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 22, 2022
Received: August 23, 2022

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,

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)*

K220953

Device Name

ChoiceSpine TigerShark™ M, Modular Interbody System

Indications for Use *(Describe)*

The ChoiceSpine TigerShark™ M, Modular Interbody System is an intervertebral body fusion device intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The device system is designed for use with autograft bone and/or allogenic bone grafts composed of cancellous and /or corticocancellous bone grafts, and with supplemental internal fixation systems (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) cleared for use in the lumbosacral spine.

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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7.0 510(k) Summary

Date:	March 31, 2022
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 TigerShark™ M, Modular Interbody System
Product Class:	Class II
Classification Name:	ChoiceSpine TigerShark™ M, Modular Interbody System • 888.3080 - Intervertebral Fusion Device with Integrated Fixation, Lumbar
Device Product Code:	ChoiceSpine TigerShark™ M, Modular Interbody System • MAX

Purpose of Submission: The purpose of this submission is to gain clearance for the new ChoiceSpine TigerShark™ M, Modular Interbody System.

Device Description: The ChoiceSpine TigerShark™ M, Modular Interbody System, consists of implants with components that are both additively and traditionally manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F3001, Class C and Ti-6Al-4V ELI per ASTM F136 respectively). The device is provided in lengths of 24-32mm and final heights of 9-17mm with 6° and 12° lordotic options and contains a hollow core to receive autogenous and / or allogenous bone graft.

Indications for Use: The ChoiceSpine TigerShark™ M, Modular Interbody System, is an intervertebral body fusion device intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with Degenerative Disc Disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The device system is designed for use with autograft bone and/or allogenic bone grafts composed of cancellous and /or corticocancellous bone grafts, and with supplemental internal fixation systems (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) cleared for use in the lumbosacral spine.

Materials: The ChoiceSpine TigerShark™ M, Modular Interbody System, implants are composed of a titanium alloy (Ti-6Al-4V ELI per ASTM F136 and ASTM F3001, Class C). The instrumentation is made from 17-4 Stainless Steel (ASTM

F899/A693), 465 Stainless Steel (ASTM F899), medical grade silicone, and polyphenylsulfone (Radel R5000 Series).

Predicate Devices:

Primary Predicate:
ChoiceSpine Octane Elevate re-branded to Octane-M (K123607)
Additional Predicates:
ChoiceSpine TigerShark™ System (K172816)

Non-clinical Testing:

Static Compression – per ASTM F2077
Static Compression Shear - per ASTM F2077
Dynamic Compression - per ASTM F2077
Dynamic Compression Shear - per ASTM F2077
Subsidence – per ASTM F2267

Substantial Equivalence Conclusion:

The implants proposed in this submission are similar to the predicate devices in the principle of operation, indications for use, biocompatibility, stabilization method, sterilization method, anatomic location and approach, product code and classification.

The implants proposed are similar to the predicate devices in material, manufacturing, post-processing steps, and locking mechanism. Mechanical and functional testing was conducted to demonstrate substantial equivalence to the predicate devices in safety, effectiveness, and performance. The subject device has components made from wrought titanium alloy (Ti-6Al-4V ELI) per ASTM F136, which the predicates do not. The system components were assessed in accordance with ISO 10993-1 and found substantially equivalent to the predicate devices.