Choice Spine, LP
Kim Finch
Director of Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

January 26, 2018

Re: K172816
Trade/Device Name: Choice Spine TiGer Shark™ System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 20, 2017
Received: December 21, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172816

Device Name
Choice Spine TiGer Shark™ System

Indications for Use *(Describe)*
Choice Spine TiGer Shark™ System:
The Choice Spine TiGer Shark™ System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six (6) months of non-operative treatment. This device is designed to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. This device is designed for use with supplemental fixation that is cleared for use in the lumbar 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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510(k) Summary

Date:	Dec 20, 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 TiGer Shark™ System
Product Class:	Class II
Classification Name:	Choice Spine TiGer Shark™ System: • 888.3080 - Spinal Intervertebral Body Fusion Device
Device Product Code:	Choice Spine TiGer Shark™ System: • MAX
Purpose of Submission:	The purpose of this submission is to gain clearance for the new Choice Spine TiGer Shark™ System, which consists of the implants which are made of Ti-6AI-4V ELI per ASTM- F3001, Class C. The subject implant devices & instrumentation will be used with additional previously cleared instrumentation.
Device Description:	The Choice Spine TiGer Shark™ System consists of implants made of titanium alloy (Ti-6Al-4V ELI per ASTM F3001, Class C). The spacers have a basic rectangular shape, a hollow center for placement of bone graft and a smooth bullet shaped distal surface. They are available in an assortment of height, length and anteroposterior angulation combinations to accommodate many different anatomic requirements. The implants are delivered via a posterior, transforaminal, or lateral approach. The devices are manufactured using the Electron Beam Melting (EBM) additive manufacturing method.
Indications for Use:	The Choice Spine TiGer Shark™ System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six (6) months of non-operative treatment. This device is designed to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. This device is designed for use with supplemental fixation that is cleared for use in the lumbar spine.

Materials: The implants are made from titanium alloy (Ti-6Al-4V ELI) per ASTM F3001, Class C and will be provided sterile. Instruments will be provided non-sterile, but will be steam sterilized before use. The instrumentation is made from 455 SS: and 17-4 SS per ASTM F899 and ASTM A564.

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
Expulsion – N/A
Subsidence – per ASTM F2267

Substantial Equivalence: The implants included in this submission are equivalent to the TranS1 Interbody Fusion System (K120991, primary predicate), and Spineart Intervertebral Fusion Device Juliet PO (K142277), Choice Spine Lumbar Spacer System, (K162103), as additional predicates.

Substantial Equivalence Conclusion: The implants proposed in this submission are identical to the predicate devices in: principle of operation, material, indications for use, biocompatibility, manufacturing and post-processing steps, stabilization method, sterilization method, anatomic location and approach, product code and classification.

The new additive manufacturing method per ASTM F3001, Class C and slight design change introduce a new worst case for design. Mechanical testing was conducted to prove that the new worst-case design is stronger, and after including all other similarities, shown to be equivalent to the predicate devices in safety, effectiveness, and performance.