ChoiceSpine, LP
Kim Finch
Director of Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37922

March 6, 2019

Re: K183397
Trade/Device Name: ChoiceSpine Stealth™ Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: February 5, 2019
Received: February 6, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Katherine D. Kavlock -S

for
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183397

Device Name
ChoiceSpine Stealth™ Cervical Spacer System

Indications for Use *(Describe)*
The ChoiceSpine Stealth™ 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 Stealth™ 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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7. 510(k) Summary

Date	February 5, 2019
Sponsor	ChoiceSpine, LP 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 Stealth™ Cervical Spacer System
Product Class	Class II
Classification Name	ChoiceSpine Stealth™ Cervical Spacer System • 888.3080 - Spinal Intervertebral Body Fusion Device
Device Product Code	ChoiceSpine Stealth™ Cervical Spacer System: • ODP
Purpose of Submission	The purpose of this submission is to gain clearance for the updated ChoiceSpine Stealth™ Cervical Spacer System. Updates to the system include new material and manufacturing (Ti-6Al-4V ELI per ASTM F3001 Class C), how supplied (sterile packed), and the addition of allogenic bone graft.
Device Description	The ChoiceSpine Stealth™ Cervical Spacer System's implants have a basic oval shape with a hollow center for placement of bone graft. The superior and inferior surfaces have angled ridges, or "teeth," for resisting migration. The spacers are available in an assortment of heights and in multiple angles of lordosis to accommodate different anatomic requirements.
Indications for Use	The ChoiceSpine Stealth™ 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 STEALTH™ 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) or polyetheretherketone (PEEK-OPTIMA® polymer, Invibio®) per ASTM F2026 with tantalum markers per ASTM F560. Both 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 and 17-4 SS per ASTM F899.
Predicate Device	**Primary predicate**: Choice Spine Cervical Interbody Spacer System (K091531), **Additional Predicate**: Choice Spine Tiger Shark System (K172816) **Additional Predicate**:NuVasive Modulus-C Interbody System (K172676)
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 spacer proposed made of Titanium (Ti-6Al-4V ELI per ASTM F3001, Class C) is identical in geometry and footprint as the PEEK spacer offered in the Stealth Cervical Spacer System. The only difference between the spacers is the material and manufacturing method which are shared with the additional predicate. The difference between the mechanical properties confirmed that the PEEK spacer is the worst-case compared to the Titanium spacer which is previously tested and cleared under K091531. 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.