May 16, 2018

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

Re: K180519
Trade/Device Name: Choice Spine HARRIER-SA™ Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: April 11, 2018
Received: April 12, 2018

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)*
K180519

Device Name
Choice Spine HARRIER-SA™ Lumbar Interbody System

Indications for Use *(Describe)*
The Choice Spine HARRIER-SA™ Lumbar Interbody System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of nonoperative treatment. This device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is designed to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The Choice Spine HARRIER-SA™ Lumbar Interbody System is a stand-alone device intended to be used with four bone screws and the accompanying anterior cover plate. Supplemental fixation, cleared by the FDA for use in the lumbosacral spine, must be used with implants ≥20°. Supplemental fixation must also be used whenever fewer than four bone screws are used. The anterior cover plate must be utilized whenever the device is implanted.

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:	April 9, 2018
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 HARRIER-SA™ Lumbar Interbody System
Product Class:	System Class II
Classification Name:	888.3080 - Intervertebral Body Fusion Device
Device Product Code:	OVD, MAX

Purpose of Submission: The purpose of this submission is to gain clearance for the new the Choice Spine HARRIER-SA™ Lumbar Interbody System.

Device Description: The Choice Spine HARRIER-SA™ Lumbar Interbody System is available in various sizes to accommodate individual patient anatomy. The Choice Spine HARRIER-SA™ Lumbar Interbody System is a stand-alone device intended to be used with (4) bone screws provided and the accompanying anterior cover plate assembly. The implant spacer components are made from two materials: Invibio PEEK-OPTIMA™ HA Enhanced and Ti-6AI-4V ELI Titanium per ASTM F3001 Class C, Tantalum markers per ASTM F560. Titanium Ti-6AI-4V ELI plate and screws per ASTM F136.

Indications for Use: The Choice Spine HARRIER-SA™ Lumbar Interbody System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. This device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is designed to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The Choice Spine HARRIER-SA™ Lumbar Interbody System is a stand-alone device intended to be used with four bone screws and the accompanying anterior cover plate. Supplemental fixation, cleared by the FDA for use in the lumbosacral spine, must be used with implants ≥20°. Supplemental fixation must also be used whenever fewer than four bone screws are used. The anterior cover plate must be utilized whenever the device is implanted.

Materials:	The implant spacer components are made from two materials: 1.Invibio PEEK-OPTIMA™ HA Enhanced 2.Ti-6AI-4V ELI Titanium per ASTM F3001, Class C Tantalum markers per ASTM F560. Titanium Ti-6AI-4V ELI plate and screws per ASTM F136. All implants except for the screws will be provided sterile. Screws will be provided non-sterile but will be steam sterilized before use. Instruments will be provided non-sterile but will be steam sterilized before use. The instrumentation is made from 455 SS and 17-4 SS, 465 SS per 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 Subsidence – per ASTM F2267
Substantial Equivalence:	The implants included in this submission are equivalent to the Spine Smith Cynch Spinal System – Visualif Interbody Fusion Implant System (K102090, primary predicate), NuVasive Lumbar Interbody Implants (K153782, additional predicate), Choice Spine TOMCAT™ Cervical Spinal System (K170953, additional predicate), and the Choice Spine TiGer Shark™ (K172816, additional predicate).
Substantial Equivalence Conclusion"	The implants proposed in this submission are similar 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 indications for use were compared, the differences include the subject device is designed to use four screws for stabilization while the primary predicate utilizes two and is cleared for use with autograft while the subject device and other predicates are intended to be used with autogenenous bone graft and /or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Mechanical testing was conducted to prove that the Choice Spine HARRIER-SA™ Lumbar Interbody System design is equivalent when compared to the predicate devices. After considering all similarities and differences to the predicate devices, the subject device has shown to be equivalent when compared to the predicate devices in safety, effectiveness, and performance.