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

July 5, 2019

Re: K191367
Trade/Device Name: Harrier-SA™ Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 6, 2019
Received: June 7, 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/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 Melissa Hall
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)*

K191367

Device Name
ChoiceSpine Harrier-SA™ Lumbar Interbody System

Indications for Use *(Describe)*

The ChoiceSpine 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 ChoiceSpine Harrier-SA™ Lumbar Interbody System is a stand-alone device intended to be used with four bone screws. 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.

☒ 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:	May 21, 2019
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 Harrier-SA™ Lumbar Interbody System
Product Class:	Class II
Classification Name:	ChoiceSpine Harrier-SA™ Lumbar Interbody System • 888.3080 - Spinal Intervertebral Body Fusion Device
Device Product Code:	ChoiceSpine Harrier-SA™ Lumbar Interbody System • MAX

Purpose of Submission: The purpose of this submission is to modify the surgical technique guide (STG) to make the use of the anterior components optional for the Harrier-SA™ Lumbar Interbody System. The intended use remains the same.

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. 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. 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.

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 and plates will be provided sterile. Screws and plates 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 – N/A
Subsidence – per ASTM F2267

Summary of technological characterstics of the subject and predicate(s):

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 difference includes the subject device is designed for use without an accompanying coverplate. However, this embodiment is similar to the additional predicate in omitting coverplate utilization. The subject device is identical to the ChoiceSpine Harrier-SA predicate aside from the required utilization of a coverplate.

Mechanical testing was conducted to prove that the Choice Spine HARRIER-SA™ Lumbar Interbody System design is equivalent when compared to the predicate devices. Dynamic Compression Shear testing of the worst-case implant construct is the standardized test that was determined to most aggressively challenge the functional performance of the device without the additional coverplate. Testing results confirm that utilization of the Harrier SA interbody and screws with or without usage of the coverplate results in equivalent functional performance. 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.

Conclusion: The implants included in this submission are equivalent to the ChoiceSpine Harrier-SA Lumbar Interbody System (K180519, primary predicate), Titan Spine Endoskeleton®TAS Interbody Fusion Device / Endoskeleton® TAS Hyperlordotic Interbody Fusion Device (K163269, additional predicate).