January 19, 2018

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

Re: K173215
Trade/Device Name: Choice Spine Laminoplasty™ Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: October 27, 2017
Received: October 30, 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,

Ronald P. Jean -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173215

Device Name
Choice Spine Laminoplasty™ Fixation System

Indications for Use *(Describe)*
Choice Spine Laminoplasty™ Fixation System:
The Choice Spine Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Choice Spine Laminoplasty Fixation System is used to hold or buttress the allograft or autograft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.

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. 510(k) Summary

Date:	Sept 25, 2017
Sponsor:	Choice Spine, 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:	Choice Spine Laminoplasty™ Fixation System
Product Class:	Class II
Classification Name:	Choice Spine Laminoplasty™ Fixation System • 888.3050 - Spinal Interlaminal Fixation Orthosis
Device Product Code:	Choice Spine Laminoplasty™ Fixation System • NQW

Purpose of Submission:	The purpose of this submission is to gain clearance for the new Choice Spine Laminoplasty™ Fixation System.
Device Description:	The proposed Choice Spine Laminoplasty Fixation System is an implant system that consists of various plates and screw configurations. The proposed plates are available in various configurations to address surgeon and patient needs as necessary. The proposed plate devices come preformed with holes for bone screws. The plate offered can be affixed to allograft or autograft material and secured with a bone screw from the system. A hinge plate is provided when additional stabilization is necessary. Screws are used to attach the plates to bone and are available in a variety of lengths and diameters to fit patient anatomy. The system components are made from medical grade Titanium Alloy Ti-6Al-4V ELI (ASTM F136), 17-4 SS (ASTM F899), 465 SS (ASTM A564), and 6061 T6 Aluminum (ASTM B221 and B209).
Indications for Use:	The Choice Spine Laminoplasty Fixation System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Choice Spine Laminoplasty Fixation System is used to hold or buttress the allograft or autograft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.
Non-Clinical Testing:	Static and Dynamic 4 Point Bend – Per ASTM F2193 Axial screw pull-out test – Per ASTM F543

Materials:	The implants are made of medical grade Titanium alloy Ti-6Al-4V ELI per ASTM F136. Instrumentation is made of medical grade 17-4 SS (ASTM F899), 465 SS (ASTM A564), and 6061 T6 Aluminum (ASTM B221 and B209).
Substantial Equivalence:	The Choice Spine Laminoplasty Fixation System is similar in design, materials and performance to the currently marketed predicates: DePuy Mountaineer (K091994), Synthes Arch Fixation System (K032534), Medtronic CENTERPIECE Plate Fixation System (K050082), and Spectrum Spine Laminoplasty Plating System (K122822). The intended use of the product as a buttress plate is substantially equivalent in performance and safety.
Substantial Equivalence Conclusion:	The Choice Spine Laminoplasty Fixation System is similar in design, materials, indications for use, intended use, classification, and performance to the currently marketed predicates: DePuy Mountaineer, the primary (K091994); additional Synthes Arch Fixation System (K032534); additional Medtronic CENTERPIECE Plate Fixation System (K050082); and additional Spectrum Spine Laminoplasty Plating System (K122822).The slight differences in the type of Ti Alloy, variation in screw and plate offerings, and selection of allograft vs autograft do not effect performance or safety of these devices. Therefore, the device is substantially equivalent.