January 3, 2019

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

Re: K183214
Trade/Device Name: Raven Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 16, 2018
Received: November 19, 2018

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,

Colin O'neill -S
for MNM

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)*
K183214

Device Name
Raven Lumbar Plate System

Indications for Use *(Describe)*
The Raven Lumbar Plate System Anterior and Lateral Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

• Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
• Pseudoarthrosis;
• Spondylolysis;
• Spondylolisthesis;
• Spinal stenosis;
• Tumors;
• Trauma (i.e. Fractures or Dislocation);
• Deformities (i.e. Scoliosis, Kyphosis or Lordosis);
• Failed Previous Fusion

The Raven Lumbar Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

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:	November 16, 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:	Raven Lumbar Plate System
Product Class:	Class II
Classification Name:	Raven Lumbar Plate System: • 888.3060 - Spinal Intervertebral Body Fixation Orthosis
Device Product Code:	Raven Lumbar Plate System: • KWQ
Purpose of Submission:	The purpose of this submission is to gain clearance for the new Raven Lumbar Plate System.
Device Description:	Raven Lumbar Plate System is an anterior/anterolateral/lateral plate system that may be used in the thoracic, lumbar, and sacral spine (T1-S1). Raven Lumbar Plate System consists of plates and screws manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136, as well as associated manual general surgical instrumentation. The implants are available in a variety of sizes to accommodate various patient anatomies.
Indications for Use:	The Raven Lumbar Plate System Anterior and Lateral Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: • Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); • Pseudoarthrosis; • Spondylolysis; • Spondylolisthesis; • Spinal stenosis; • Tumors; • Trauma (i.e. Fractures or Dislocation); • Deformities (i.e. Scoliosis, Kyphosis or Lordosis); • Failed Previous Fusion

	The Raven Lumbar Plate System Buttress Plate is intended to stabilize the allograft or autograft at one level (T1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.
Summary of the Technological Characteristics:	As established in this submission, the Raven Lumbar Plate System is substantially equivalent and has similar technological characteristics to its predicate devices through comparison in areas including intended use, material composition, principles of operation, and design.
Summary of the Performance Data:	Risk analysis was performed to demonstrate that the Raven Lumbar Plate System is substantially equivalent to its predicate devices. The risk analysis determined that the predefined acceptance criteria associated with the following mechanical testing was met: • Static and dynamic compression testing per ASTM F1717-15 • Static torsion testing per ASTM F1717-15
Conclusion:	The Raven Lumbar Plate System has similar indications, technological characteristics, and principles of operation as its predicates. The risk analysis performed demonstrates that any minor differences do not impact device performance a compared to the predicates. The Raven Lumbar Plate System was shown to be substantially equivalent to its predicate devices.
Predicate Device:	**Primary predicate**: Stryker Spine LITe® Plate System (K150449), **Additional Predicate**: Corelink, LLC Zou Anterior Lumbar Plate System (K121791), and Meditech Spine, LLC Cure™ Lumbar Plate System (K171538), Altiva Corporation, Altes Anterior Buttress Plating System (K061482), Globus, Plymouth Thoracolumbar Plate System (K120092).