JUL 16 2014

510(k) Summary for the 9 mm Wide Choice Spine Lumbar Spacer System

Date Prepared: July 14, 2014

Submitter Contact: Choice Spine, LP.
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Regulatory Contact: Kim Finch, Manager of Regulatory Affairs

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Device Name: Spinal Vertebral Body Replacement Device
Intervertebral Fusion Device with Bone Graft, lumbar

Trade Name: Choice Spine Lumbar Spacer System (Sabre, Shark, Hornet, Harpoon)

Product Class: Class II

Regulation Number 888.3080 Intervertebral Body Fusion Device

888.3060 Spinal Intervertebral body fixation orthosis

Product Codes: MAX, MQP

Panel Code: 87

Indications for Use:

When used as an intervertebral body fusion device, Choice Spine lumbar Spacers are indicated for intervertebral body fusion of the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment. The 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. The device system is designed for use with supplemental fixation systems such as (ORIA Claris, ORIA Spinal Clip System, etc.).

When used as a vertebral body replacement device, Choice Spine lumbar Spacers are intended for use in the thoracic and lumbar spine, from T1 to L5, for the replacement of a collapsed or unstable vertebral body resulting from a tumor or traumatic injury. The device system is designed for use with supplemental fixation (ORIA Claris, ORIA Spinal Clip System, etc.) and with autograft bone to facilitate fusion.

Device Descriptions:

The 9mm width spacer system (SABRE, SHARK, HORNET, HARPOON) has a rectangular shape, a hollow center for placement of autograft bone, and a smooth anterior surface (nose). It is available in a variety of heights, length, and lordosis combinations with and without medial-lateral curvature to accommodate many different anatomic requirements.

Materials:

The 9mm width spacers are manufactured from PEEK OPTIMA LT1(Invibio) per ASTM F2026. The spacer includes tantalum marking pins per ASTM F560 for radiographic assistance. These technological characteristics and materials are identical to the predicate devices.

The 9mm width trials are manufactured from 17-4 Stainless Steel per ASTM F899 and are biocompatible.

Predicate Device(s):

K2M, LLC Aleutian Spacer System K051454, K130699
Innovasis, Inc., Box Peek VBR System K062151
Choice Spine Lumbar Spacer System, K073669

Performance Standards:

Performance testing was completed by an independent laboratory following ASTM F2077-11 and ASTM F2267-04. The tests included static axial compression bending, static torsion, dynamic axial compression bending and dynamic torsion testing. The test methods and results are substantially equivalent to those of the predicate devices.

Conclusion:

The 9 mm wide spacer has the same technological characteristics, intended use, comparable performance data, and is manufactured using the same processes as the predicate devices. The sterilization method and parameters remain the same. In conclusion, the 9 mm wide devices are substantially equivalent to the listed predicates and do not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 16, 2014

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

Re: K140142
Trade/Device Name: Choice Spine Lumbar Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: June 13, 2014
Received: June 16, 2014

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement K140142

The Company's Indications for Use Statement for Choice Spine Lumbar Spacer System is provided.

Indications for Use:

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Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)