K091926 (½)

DEC 22 2009

510(k) Summary

Sponsor:

Choice Spine, LP
306 Erin Drive
Knoxville, TN 37919
ph: 865.246.3333
fax: 865.588.4045

Contact:

G. Todd Hawkins
Director of Regulatory Affairs/Quality Assurance

Trade Name:

Choice Spine Anterior Cervical Plate (ACP) System

Common Name:

Anterior Cervical Plate, Anterior Cervical Spinal Fixation System

Classification Name:

888.3060 – Spinal intervertebral body fixation orthosis

Device Product Code:

KWQ

Device Description:

The *Choice Spine Anterior Cervical Plate (ACP) System* is an anterior cervical spinal fixation system consisting of plates and screws. The plates are available in multiple lengths to accommodate single or multi-level surgeries and different anatomies.

Intended Use:

The *Choice Spine Anterior Cervical Plate (ACP) System* is intended for anterior screw fixation of the cervical spine (levels C2 to C7) and is designed to provide stabilization as an adjunct to spinal fusion at these levels. Indications for the use of this device include: failed previous fusion, pseudoarthrosis, tumor, deformity, spinal stenosis, trauma, spondylolisthesis, or degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

WARNING: The *Choice Spine ACP System* is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

510(k) Summary (continued)

Materials:

The *Choice Spine Anterior Cervical Plate (ACP) System* plates and screws are manufactured from titanium alloy (Ti6Al4V ELI; according to ASTM F136). The plates incorporate a screw-retention mechanism ("clip"), which is manufactured from wrought nickel-titanium alloy (NiTi; according to ASTM F2063).

Substantial Equivalence:

Documentation was provided that demonstrates the *Choice Spine ACP System* to be substantially equivalent to a previously cleared device. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, primary material of manufacture, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Choice Spine, LP
% G. Todd Hawkins
306 Erin Drive
Knoxville, TN 37919

DEC 22 2009

Re: K091926
Trade/Device Name: Choice Spine Anterior Cervical Plate (ACP) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 16, 2009
Received: December 17, 2009

Dear Mr. Hawkins:

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 (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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K091926

Device Name: ***Choice Spine Anterior Cervical Plate (ACP) System***

Indications for Use:

The *Choice Spine Anterior Cervical Plate (ACP) System* is intended for anterior screw fixation of the cervical spine (levels C2 to C7) and is designed to provide stabilization as an adjunct to spinal fusion at these levels. Indications for the use of this device include: failed previous fusion, pseudoarthrosis, tumor, deformity, spinal stenosis, trauma, spondylolisthesis, or degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091926