510(k) Summary

JAN 27 2010

Sponsor:

RSB Spine, LLC
3030 Superior Ave., Suite 703
Cleveland, OH 44114
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Contact Person: James M. Moran, D. Eng.
Vice President of Engineering and Chief Technical Officer

Trade Name: InterPlate™ C-PS and L-PS Interbody Spacers

Device Classification Class II

Classification Name: Intervertebral body fusion device

Regulation: 888.3080

Device Product Code: ODP, MAX

Device Description: The C-PS comprises a closed annular ring, a hollow center for placement of bone graft and sawtooth "teeth" on the inferior and superior surfaces for resisting migration and expulsion.

The L-PS comprises a closed annular ring with integral anteroposterior cross-piece, a hollow center for placement of bone graft and sawtooth "teeth" on the inferior and superior surfaces for resisting migration and expulsion.

Materials: The C-PS and L-PS are manufactured from polyetheretherketone (PEEK-OPTIMA® LT1, Invibio™) as described by ASTM F2026. Radiopaque markers are manufactured from titanium alloy (Ti-6Al-4V) according to ASTM F136.

Intended Use: The C-PS is indicated for intervertebral body fusion of the cervical spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space. The C-PS is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The C-PS is intended to be used with a supplemental internal fixation system.

The The L-PS is indicated for intervertebral body fusion of the lumbar spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space. The L-PS System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, 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 lumbar device is to be used in patients who have had six months of non-operative treatment. The L-PS is intended to be used with a supplemental internal fixation system.

Substantial Equivalence:

Documentation was provided which demonstrated the C-PS and L-PS to be substantially equivalent to the previously cleared devices including the InterPlate™ PEEK Cervical IFD (K081194), Pioneer Cervical IBF (K073177), Pioneer vertebral spacer (K043206), InterPlate™ IFD (K071922) and the MC+ (K043479). The substantial equivalence is based upon equivalence in basic design, intended use, indications, performance and anatomic sites.

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

JAN 27 2010

RSB Spine, LLC
% Mr. James M. Moran, D. Eng.
Vice President of Engineering and
Chief Technical Office
3030 Superior Avenue, Suite 703
Cleveland, Ohio 44114

Re: K092540
Trade/Device Name: InterPlate™ C-PS and L-PS Interbody Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: December 28, 2009
Received: December 28, 2009

Dear Mr. Moran:

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 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: **K092540**

Device Name: **InterPlate™ C-PS and L-PS Interbody Spacers**

Indications for Use:

The C-PS is indicated for intervertebral body fusion of the cervical spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space. The C-PS is intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment. The C-PS is intended to be used with a supplemental internal fixation system.

The L-PS is indicated for intervertebral body fusion of the lumbar spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space. The L-PS System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, 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 lumbar device is to be used in patients who have had six months of non-operative treatment. The L-PS is intended to be used with a supplemental internal fixation system.

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K092540