K090566

Section 22. 510(k) Summary

JUN - 1 2009

As Required By Section 807.92(c)

Submitter: Custom Spine
1140 Parsippany Blvd, Suite 201
Parsippany, NJ 07054

Contact Person: Saad Attiyah
Manager of Regulatory Affairs and Quality Assurance
Voice: (973) 265-5036
Fax: (973) 808-0707

Date Prepared: May 15, 2009

Device Class: II

Classification Names: Per 21 CFR § 888.3080, Intervertebral Body Fusion Device

Classification Panel: Orthopedics

Product Code: MAX
Proprietary Name: PATHWAY AVID

Predicate Devices: Spinal Elements Lucent® (K071724)
Depuy Acromed™ Stackable Cage™ System
(K990148, K001340, K030833)
Vertebration XYcor™ (K070082)

Device Description: The PATHWAY *AVID* Intervertbral Body Fusion Device is made From PEEK Optima. The device is made from multiple PEEK segments. The segments are serrated on the superior and inferior surfaces. The PEEK segments are attached with titanium pins and have a titanium linkage that attaches the segments. This pins and the linkage provide the means to form into its final articulated shape.

The titanium alloy pins serve as markers providing visual aid in determining the location of the implant both intra and postoperatively.

The articulated device foot print ranges from 8 mm through 14 mm in height, 20mm in width and 35 mm in length.

The implants are non-sterile and instruments are provided clean and non-sterile. These devices are to be sterilized by the user facility.

Intended Use: The PATHWAY Intervertebral body fusion device is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The patient may have had a previous non-fusion spinal surgery at the involved level(s).

The device is intended to be used with supplemental spinal fixation systems that have been cleared for lumbosacral spine (I.e. posterior pedicle screws and rods systems and anterior screw and rod systems). The device is intended to be used with autogenous bone graft.

	Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PATHWAY AVID device. The PATHWAY AVID Intervertebral body fusion device must be inserted using a transforaminal approach.
Materials:	This product is manufactured from Polyetheretherketone (PEEK) as per ASTM F2026 and contains titanium (Ti-6Al-4V) as per ASTM F136, implant grade titanium.
Performance Data:	Performance data per ASTM 2077 and ASTM 2267 and compared to the predicate devices. In addition, cadaver testing demonstrated the PATHWAY AVID is substantially equivalent to its predicates, as it was shown that the device can be used as intended by the intended user population per its labeling following a standard training program.
Summary of Technological Characteristics	PATHWAY AVID has been evaluated in accordance with the "Class II Special Controls Guidance Document: Intervertebral Body Fusion Devices", June 12, 2007 and demonstrates substantial equivalent performance to the identified predicate device systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Custom Spine, Inc.
% Saad Attiyah
1140 Parsippany Blvd., Suite 201
Parsippany, NJ 07054

JUN - 1 2009

Re: K090566
Trade/Device Name: Pathway Avid
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: February 19, 2009
Received: March 3, 2009

Dear Mr. Attiyah:

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.

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/cdrh/comp/ 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

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Section 6. Indication For Use

The PATHWAY Intervertebral body fusion device is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The patient may have had a previous non-fusion spinal surgery at the involved level(s).

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Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PATHWAY AVID device.

The PATHWAY AVID Intervertebral body fusion device must be inserted using a transforaminal approach.

Prescription Use __X__ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 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)
for Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090566