K111774

JUL 20 2011

VIII. 510(k) Summary

As Required Per 21 CFR 807.92(a)

Name of Firm
Custom Spine, Incorporated
1140 Parsippany Blvd, Suite 201
Parsippany, NJ 07054
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Official Correspondent
Saad Attiyah
Manager of Regulatory Affairs and Quality Assurance
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Establishment Number
3005129649

Device Name
Legally Market Trade Name: PATHWAY
Common Name: Intervertebral Interbody Fusion Devices
Device Classification: Class II
Regulation Number: 21 CFR 888.3080
Device Product Codes: MAX

Predicate Devices
Custom Spine PATHWAY (K080281)

Indications for Use
The PATHWAY Interbody Fusion Device(s) is intended for spinal fusion procedure at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative Disc Diseases (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

The PATHWAY Interbody Fusion device is intended to be used with supplemental spinal fixation systems that have been cleared for lumbosacral spine (i.e. posterior pedicle screws and rod systems,

anterior plate systems, and anterior screw and rod systems. The device(s) is intended to be used with autogenous bone graft.

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

The PATHWAY device can be used in one of two methods:

Transforaminal Lumbar Interbody Fusion (TLIF)
Used as a TLIF, a single device is implanted in the appropriate location (L2-S1) to provide support for a transforaminal approached surgery.

Posterior Lumbar Interbody Fusion (PLIF)

Used as a PLIF, two devices are implanted in the appropriate locations (L2-S1) to provide support to the spine for a posterior surgery.

Performance Data
Performance Data was originally performed on the PATHWAY Device (K080281). The proposed changes do not impact the mechanical performance of the device.

Description of Modified Device
The proposed modification to the PATHWAY Intervertebral Body Fusion Devices (PLIF and TLIF) is to provide a tantalum radiographic marker along with the currently cleared titanium (Ti-6Al-4V) markers.

Substantial Equivalence
The proposed change to the PATHWAY (PLIF/TLIF) has the same intended use, principles of operation, and technological characteristics and identical indications for use as the predicate PATHWAY. There are no differences in the PATHWAY (PLIF/TLIF) technological characteristics or principles of operation, thus the device does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Custom Spine, Inc.
% Mr. Saad Attiyah
Manager of Regulatory Affairs and Quality Assurance
1140 Parsippany Boulevard, Suite 201
Parsippany, New Jersey 07054

JUL 20 2011

Re: K111774
Trade/Device Name: PATHWAY Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 21, 2011
Received: June 23, 2011

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. 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,

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

Enclosure

Section VII. Indications for Use

510(k) Number (if known): K111774
Device Name: PATHWAY

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K111774