K083425

510(k) Summary
for the Fusion Advantage Interbody Cages

MAR 2 0 2009

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Fusion Advantage Interbody Cages

Date Prepared: February 12, 2008

1. **Submitter:**
Adaptive Specialty, LLC
25 NW 23rd PL, STE 6 - 347
Portland, OR 97210

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

~~MAR 1 0 2009~~

2. **Trade name:** Fusion Advantage Interbody Cages
Common Name: intervertebral body fusion device
Classification Name: intervertebral body fusion device - cervical
Intervertebral body fusion device - lumbar
21 CFR section 888.3080
ODP/MAX
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
The Fusion Advantage Interbody Cages are substantially equivalent to similar previously cleared cervical and lumbar intervertebral body fusion devices.

4. **Description of the device:**
The Adaptive Specialty Fusion Advantage cervical cage was developed as an intercorporal implant for anterior cervical spondylodesis. The Fusion Advantage System was especially adapted to the local anatomy in order to secure the surgical result as well as possible. Its inferior and superior sides are flat with ridges on both surfaces to prevent migration. The implant is oval shaped with a large central graft space to help facilitate bony integration once implanted. In the lateral view, the implant has a 2.5° lordotic form.

The Adaptive Specialty Fusion Advantage Lumbar cage was developed as an implant for the posterior stabilization of the lumbar spinal column. The Adaptive Specialty Fusion Advantage implant has ridges on both its inferior and superior surfaces to prevent migration. It is a rectangular shape with a large rectangular graft space and lateral holes help facilitate bony integration once implanted.

Materials:
PEEK-OPTIMA LT1 polymer (ASTM F2026 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications)

Function:
To maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion.

5. **Intended Use:**
Fusion Advantage Cervical Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Fusion Advantage Cervical Cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. Fusion Advantage Cervical Cages are to be used with

supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Fusion Advantage Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Fusion Advantage Lumbar Cage implants are to be used with autogenous bone graft and implanted via an open posterior, transforaminal or lateral approach. The Fusion Advantage Lumbar Cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

6. **Comparison of the technological characteristics of the device** to **predicate and legally marketed devices:**

   The Fusion Advantage Interbody Cages have the same indications and material, and similar designs as previously cleared devices.

7. **Summary of Nonclincal Tests**

   Tests performed according to ASTM F2077/F2267 indicate that the Interbody Fusion Advantage Interbody Cages meet required mechanical strengths.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Adaptive Specialty, LLC
% The Orthomedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

MAR 2 0 2009

Re: K083425
Trade/Device Name: Fusion Advantage Cervical Cages, Fusion Advantage Lumbar Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP, MAX
Dated: February 19, 2009
Received: February 19, 2009

Dear Mr. Webb:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K083425

Device Name: Fusion Advantage Cervical Cages

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083425

Indications for Use

510(k) Number (if known): K083425

Device Name: Fusion Advantage Lumbar Cages

Indications for Use:

The Fusion Advantage Lumbar Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Fusion Advantage Lumbar Cage implants are to be used with autogenous bone graft and implanted via an open posterior, transforaminal or an lateral approach. The Fusion Advantage Lumbar Cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

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Concurrence of CDRH, Office of Device Evaluation (ODE)