K073202

ABBOTT SPINE, INC.
SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	Abbott Spine Inc.
ESTABLISHMENT REGISTRATION NUMBER:	1649384 JAN 30
CONTACT PERSON:	Maritza Elias Regulatory Affairs Specialist Telephone: 512.533.1908 Fax: 512.918.2784
DATE:	January 16, 2008
TRADE NAME:	Ardis™ Spacer
PRODUCT CODE:	MAX
DEVICE CLASSIFICATION:	Class II
CLASSIFICATION NAME:	Spinal Intervertebral Body Fusion Device
CLASSIFICATION REFERENCE:	21 CFR § 888.3080
PREDICATE DEVICE:	BAK™ Interbody Fusion System (P950002)
DEVICE DESCRIPTION:	Ardis™ Spacer is a hollow device intended for use as an intervertebral body fusion device in the lumbosacral region (L2-S1) of the spine.
INDICATIONS:	The Ardis™ Spacer is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment. The Ardis™ Spacer is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

SUBSTANTIAL EQUIVALENCE:

Engineering evaluations and bench testing were conducted to assess the physical and mechanical properties of the subject device. These results demonstrate that the performance of the Abbott Spine Ardis™ Spacer, when compared with other available intervertebral body fusion devices with similar indications, intended use and materials of manufacture is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2008

Abbott Spine, Inc.
% Ms. Maritza Elias
Regulatory Affairs Specialist
5301 Riata Park Court, Bldg F
Austin, TX 78727

Re: K073202
Trade/Device Name: Ardis™ Spacer
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: November 7, 2007
Received: November 13, 2007

Dear Ms. Elias:

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 Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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): K073202

Device Name:

Abbott Spine Ardis™ Spacer

Indications for Use:

The Ardis™ Spacer is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment.

The Ardis™ Spacer is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

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 General, Restorative, and Neurological Devices

510(k) Number K073202