MAY - 4 2005

510(k) Summary of Safety and Effectiveness

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

K050060

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Contact:	Mr. Hartmut Loch, RAC Regulatory Consultant & Official FDA Correspondent for Allez Spine, LLC. President, HHL Consulting Tel: 619-885-7733 Fax: 760-632-9133 c/o Allez Spine, LLC. 19772 Mac Arthur Blvd., Suite 150 Irvine, CA 92612
Trade name:	Allez Spine *Laguna*™ Pedicle Screw System
Common name:	Spinal Fixation System
Classification name:	Appliance, Fixation, Spinal Interlaminal - § 888.3050 (KWP) Appliance, Fixation, Spinal Intervertebral - § 888.3060 (KWQ) Orthosis, Spinal Pedicle Fixation - § 888.3070 (MNI) Orthosis, SpondylolisthesisSpinal Fixation - § 888.3070 (MNH) All Class II, Orthopedic Device Panel 87
Product Code:	KWP, KWQ, MNI & MNH
Device Description and Characteristics:	The *Laguna*™ Pedicle Screw System is intended to help provide correction, immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral space. The Laguna Spinal System consists of a variety of rods and screws, which can be rigidly locked into a variety of configurations, with each construct being tailor made for the individual case. Multi axial implant screws are supplied in 5mm, 6mm, 7mm and 8mm diameter sizes. All sizes are able to receive 5.5mm connecting rods only. The Laguna Spinal System implant components are fabricated from medical grade titanium alloy described by such standards as ASTM F136 or ISO 5832-3 or 5832-2.
Equivalence:	Allez Spine *Laguna*™ Pedicle Screw System is substantially equivalent to the CD HORIZON Spinal System, which is manufactured and marketed by Medtronic Sofamore Danek K981676 S/E January 28, 1999
Indications:	The Laguna Spinal System is intended for posterior, non-cervical fixation for the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis and/or lordosis); tumor pseudarthrosis; and/or failed previous fusion.
Performance data:	Biomechanical tests have been performed. The test results were equivalent to other similar implants and are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

Allez Spine, LLC
C/o Mr. Hartmut Loch, RAC
HHL Consulting, Inc.
2009 Freda Lane
Cardiff, California 92007

Re: K050060
Trade/Device Name: LAGUNA™ Pedicle Screw System
Regulation Number: 21 CFR 888.3050, 888.3060, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, KWP, KWQ, MNH
Dated: April 15, 2005
Received: April 18, 2005

Dear Mr. Loch:

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.

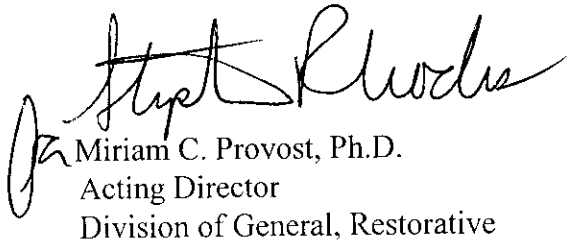
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting 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): K050060

Device Name: LAGUNA™ Pedicle Screw System

Indications For Use:

The Laguna Spinal System is intended for posterior, non-cervical fixation for the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e.fracture or dislocation); spinal stenosis; curvatures (i.e.scoliosis, kyphosis and/or lordosis); tumor pseudarthrosis; and/or failed previous fusion.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K050060