K072672

ABBOTT SPINE
510(K) SUMMARY

SUBMITTER:	Abbott Spine
ESTABLISHMENT REGISTRATION NUMBER:	1649384
CONTACT PERSON:	David Padgett Specialist, Regulatory Affairs Telephone: (512) 533-1998 Fax: (512) 258-0995
DATE:	20 September 2007
TRADE NAME:	Sequoia Spinal System
COMMON NAME:	Spinal Fixation System
CLASSIFICATION NAME:	SPINAL FIXATION SYSTEM
CLASSIFICATION REFERENCE:	21 CFR § 888.3070 (MNH, MNI, NKB)
PREDICATE DEVICE:	InCompass® Spinal Fixation System, K021564, Abbott Spine, cleared 10/25/02 InCompass® Special 510(k), K023644, Abbott Spine, cleared 11/25/02

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DEVICE DESCRIPTION:

The Sequoia Spinal System consists of various open style screws, rods and connectors and is intended to provide temporary stabilization following surgery to fuse the spine. This system includes titanium spinal rods in varying lengths. Additionally included are screws with a polyaxial design, allowing the surgeon to use a top loading technique for dropping the spinal rod down to the fixation components into a u-shaped opening.

INDICATIONS:

When intended for pedicle screw fixation from T1-S1, the indications include immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, and failed previous fusion.

As a pedicle screw system placed between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine (T1-S1), the indications are idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), tumor, spondylolisthesis, spinal stenosis and failed previous fusion.

When intended for anterolateral screw, rod and or cable fixation of the T6-L5 spine the indications are degenerative disc disease (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, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion

After solid fusion occurs, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

The use of posterior spinal instrumentation in children has been reported in the literature. Sequoia may be used for non-pedicle posterior use in this patient group.

COMPARISON TO PREDICATE DEVICE:	The subject device is the result of modifications to the existing InCompass® Spinal Fixation System. The subject device has the same intended use and is substantially equivalent to the aforementioned predicate device.
PERFORMANCE DATA (NONCLINICAL AND/OR CLINICAL):	Non-Clinical Performance and Conclusions: Laboratory and bench testing results demonstrate that the proposed device is substantially equivalent to the predicate device. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Abbott Spine
% Mr. David Padgett
Specialist, Regulatory Affairs
5301 Riata Park Court, Bldg. F
Austin, Texas 78727

NOV 2 8 2007

Re: K072672
Trade/Device Name: Sequoia Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: III
Product Code: NKB, MNI, MNH
Dated: November 5, 2007
Received: November 6, 2007

Dear Mr. Padgett:

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 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,

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): TBD

Device Name: Abbott Spine **Sequoia Spinal System**

Indications for Use:

When intended for pedicle screw fixation from T1 –S1, the Sequoia Thoracolumbar Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

As pedicle screw system places between L3 and S1, the indications include Grade 3 or Grade 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after the solid fusion is established.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine (T1-S1), the indications are idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degenerative of the disc confirmed by history and radiographic studies), tumor, spondylolisthesis, spinal stenosis and failed previous fusion.

When intended for anterolateral screw, rod and/or cable fixation of the T6-L5 spine, the indications are degenerative disc disease (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, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K07 2672

Indications for Use

510(k) Number (if known): TBD

Device Name: Abbott Spine **Sequoia Spinal System**

After solid fusion occurs, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

The use of posterior spinal instrumentation in children has been reported in the literature. The Sequoia Spinal System may be used for non-pedicle posterior use in this patient group.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K072672