MAR - 4 2004

510(k) Summary
K033965

SUBMITTED BY

Diane Johnson
On Behalf of Spine Next America
8381 Dix Ellis Trail
Suite 110
Jacksonville, FL 32256

Date Submitted: December 19, 2003

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Trade/Proprietary Name:	Spine Next SHIRAZ Anterior System
Common/Usual Name:	Spinal Fixation System
Classification Names:	Spinal intervertebral body fixation orthosis

PREDICATE DEVICE

Moss Miami [K021880, cleared June 26, 2002].
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92

DEVICE DESCRIPTION AND MATERIALS OF CONSTRUCTION

The Spine Next SHIRAZ Anterior System is designed to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

All implants are manufactured from Titanium Alloy (Ti6Al4V) meeting the requirements of ASTM F136/ISO 5832 or commercially pure Titanium (cpTi, Grade 4) meeting requirements of ASTM F67/ISO 5832.

INDICATIONS FOR USE

The SHIRAZ systems include the SHIRAZ JAVA, the SHIRAZ Posterior, and the SHIRAZ Anterior System. The SHIRAZ JAVA system has been previously cleared.

When used as a pedicle screw fixation system, the SHIRAZ Systems are intended for treatment of severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint in skeletally mature patients receiving fusion by autogenous bone

grafting having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

When used as a pedicle screw fixation system, the SHIRAZ Systems are also 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 spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

When used as a posterior, noncervical hook, and/or sacral/iliac screws fixation system, or as an bi-lateral anterior, thoracic/lumbar screw fixation system, the SHIRAZ Systems are intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., disogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

PERFORMANCE DATA

Biomechanical testing, including static and dynamic testing, was performed in accordance with ASTM F1717 and ASTM 1798.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 2004

Spine Next America
C/o Ms. Diane Johnson
Director, Regulatory Affairs
104 Greenwood Creek Road
Queenstown, MD 21658

Re: K033965
Trade/Device Name: SHIRAZ Anterior System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 20, 2003
Received: December 22, 2003

Dear Ms. Johnson:

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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033965

Device Name: Spine Next SHIRAZ Anterior System, a portion of the SHIRAZ Systems.

Indications for Use for the SHIRAZ Systems:

When used as a pedicle screw fixation system, the SHIRAZ Systems are intended for treatment of severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar - first sacral (L5-S1) vertebral joint in skeletally mature patients receiving fusion by autogenous bone grafting having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

When used as a pedicle screw fixation system, the SHIRAZ Systems are also 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 spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

When used as a posterior, noncervical hook, and/or sacral/iliac screws fixation system, or as an bi-lateral anterior, thoracic/lumbar screw fixation system, the SHIRAZ Systems are intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., disogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

K033965

Prescription Use X
(PER 21 CFR 801.109)

OR **Over-The-Counter Use**

Optional Format 1-2-96