K021507

AUG 01 2002

SpineVision™

Spine systems for specialists

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	SpineVision, Inc. 3003 Summit Blvd., Suite 1500 Atlanta, GA 30319 Phone: 404-460-5077
510(K) CONTACT:	Lynnette Whitaker Vice President, Regulatory Affairs 574-269-3701
TRADE NAME:	PLUS™ Pivot Link Universal System
COMMON NAME:	Rod, Hook, and Screw Spinal Instrumentation
CLASSIFICATION:	888.3050 Spinal Interlaminal Fixation Orthosis 888.3070 Pedicle Screw Spinal System
DEVICE PRODUCT CODE:	Product code: 87 KWP, MNH, MNI
SUBSTANTIALLY EQUIVALENT DEVICES:	PLUS Pivot Link Spinal System, SpineVision, Inc.

DEVICE DESCRIPTION AND INTENDED USE:
The PLUS Pivot Link Universal System spinal instrumentation consists of hooks, screws, rods, and connectors that can be assembled in a variety of constructs. The instrumentation is combined and placed to treat a variety of spinal disorders, with the constructs varying according to the nature of the spinal pathology. The PLUS System components are available in stainless steel according to ASTMs F138 and F1586, from titanium alloy complying with ASTM-F136, and from commercially pure Titanium complying with ASTM F67.

K021507

INDICATIONS FOR USE

When used as a posterior, non-pedicle system of the noncervical spine, the PLUS™ Pivot Link Universal System is indicated for:

- degenerative disc disease (discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- fracture
- spinal stenosis
- deformities (i.e. scoliosis, kyphosis, lordosis)
- tumors
- failed previous fusion (pseudoarthrosis)

The PLUS Pivot Link Universal System is also a pedicle screw system indicated for skeletally mature patients who:

- have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;
- receive fusions using autogenous bone graft only;
- have the device fixed or attached to the lumbar and sacral spine (L3 to sacrum); and
- have the device removed after the development of a solid fusion.

In addition, the PLUS Pivot Link Universal System is a pedicle screw system 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
- failed previous fusion (pseudoarthrosis)

BASIS OF SUBSTANTIAL EQUIVALENCE:

The components of the PLUS Pivot Link Universal System are identical in design, material, and intended use to other spinal instrumentation system that have been cleared by FDA for posterior spinal use. Mechanical testing was performed to demonstrate the equivalence of the construct design to currently marketed spinal systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2002

Ms. Lynnette Whitaker
Vice President, Regulatory Affairs
SpineVision, Incorporated
3003 Summit Boulevard, Suite 1500
Atlanta, Georgia 30319

Re: K021507
Trade/Device Name: PLUS™ Pivot Link Universal System
Regulation Number: 888.3050 and 888.3070
Regulation Name: Spinal Interlaminal Fixation Orthosis, Pedicle Screw Spinal System and Spondylolisthesis Spinal Fixation Device System
Regulatory Class: II
Product Code: KWP, MNI, and MNH
Dated: May 8, 2002
Received: May 9, 2002

Dear Ms. Whitaker:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Melkerson

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) K021507

Device Name: PLUS™ Pivot Link Universal System, Additional Components

Indications for Use:

When used as a posterior, non-pedicle system of the noncervical spine, the PLUS™ Pivot Link Universal System is indicated for:

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- fracture
- dislocation
- scoliosis
- kyphosis
- spinal tumor
- failed previous fusion (pseudoarthrosis)

Concurrence of CDRH, Office of Device Evaluation

for Mark N Milhern

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

510(k) Number K021507

Prescription Use _____ OR Over-The Counter Use ____
(Per 21 CFR 801.109)