

NOV 23 2004

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**NAME OF FIRM:** SpineVision, Inc.  
3003 Summit Blvd., Suite 1400  
Atlanta, GA 30319  
Phone: 404-460-5077

**510(K) CONTACT:** Lynnette Whitaker  
Vice President, Regulatory Affairs  
574-269-9776

**TRADE NAME:** Uni-Thread™ Spinal System

**COMMON NAME:** Rod and Screw Spinal Instrumentation

**CLASSIFICATION:** 888.3070 Pedicle Screw Spinal System

**DEVICE PRODUCT CODE:** Product code: 87 MNH, MNI

**SUBSTANTIALLY EQUIVALENT DEVICES:** Uni-Thread Spinal System, SpineVision, Inc., K013301 and K021510  
Pathfinder System, Spinal Concepts, Inc., K030625

**DEVICE DESCRIPTION AND INTENDED USE:**

The Uni-Thread Spinal System instrumentation consists of 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 Uni-Thread System components are available in titanium alloy manufactured according to ASTM-F136.

**INDICATIONS FOR USE**

The Uni-Thread Spinal System is 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 Uni-Thread Spinal 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 Uni-Thread Spinal 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.



NOV 23 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Lynnette Whitaker  
Vice President, Regulatory Affairs  
SpineVision, Inc.  
3003 Summit Boulevard, Suite 1400  
Atlanta, Georgia 30319

Re: K042640  
Trade/Device Name: Uni-Thread Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: II  
Product Code: MNH, MNI  
Dated: September 23, 2004  
Received: September 27, 2004

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.

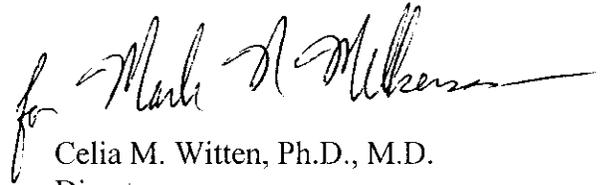
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Lynnette Whitaker

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) 276-0120. 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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the printed name.

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

## Indications for Use

510(k) Number (if known): K042640

Device Name: Uni-Thread Spinal System

### Indications For Use:

The Uni-Thread Spinal System is a pedicle screw system indicated for skeletally mature patients who:

- have severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebra;
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- fracture
- dislocation
- scoliosis
- kyphosis
- spinal tumor
- failed previous fusion (pseudoarthrosis)

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark A. Miller*  
(Division Sign-Off)

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**Division of General, Restorative,  
and Neurological Devices**

510(k) Number   K042640