OCT 2 2 2003

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SIGNUS Medical, LLC.

Contact Person: Mr. Thomas Hoghaug, Managing Director
SIGNUS Medical LLC
6713 Lakeway Drive
Chanhassen, MN 55317
Telephone: (952) 974-9456
Fax: (952) 975-0465

Date Prepared: May 5, 2003

Trade Name: The ConKlusion Pedicle Screw System

Classification, Name and Number: Class II
Pedicle Screw System
21 CFR 888.3070

Product Code: MNI and MNH

Predicate Device(s): The subject device is substantially equivalent to the following devices:

- Plus Pivot Link Universal System (K022271), manufactured by SpineVision, Inc.
- Global Spinal Fixation System (K001668), manufactured by D.K.M Co., LTD.
- Triple-Fix Spinal Fixation System (K992147), manufactured by Advanced Spine Technology, Inc.

Device Description: The ConKlusion Pedicle Screw System is a spinal system that consists of a variety of hooks, screws, rods, connectors, and associated instruments. Fixation is provided by bone (pedicular) screws inserted into the vertebral body of the spine using posterior approach.

Intended Use: The Conklusion Pedicle Screw System, including hook, 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 instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture,

dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, this device is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to S1) with removal of the implants after the attainment of a solid fusion.

Functional and Safety Testing:

Mechanical testing of the subject device consisted of three static mechanical tests and one dynamic test to evaluate the spinal implant assemblies. The three static mechanical tests are compression bending, tensile bending, and torsion. The dynamic test is compression bending fatigue. All testing was conducted in accordance with ASTM F1717. The result of the testing was successful. The device performed as designed and met, or exceeded, all product specifications.

Conclusion:

SIGNUS Medical LLC considers the ConKlusion Pedicle Screw System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

SIGNUS Medical, LLC
C/o Ms. Tracy L. Gray, R.N., B.S., RAC
Senior Consultant
Alquest, Inc.
4050 Olson Memorial Hwy., Suite 350
Minneapolis, Minnesota 55422

Re: K031455
Trade Name: Conklusion® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: September 8, 2003
Received: September 9, 2003

Dear Ms. Gray:

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" (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,

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

K031455

- **Indications for Use Page**

Device Name: The Conklusion® Pedicle Screw System

The Conklusion Pedicle Screw System, including hooks, 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 instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

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

510(k) Number K031455