K050965

Appendix II

510 (k) Summary

Prepared 4/15/2005

JUN 14 2005

Submitter Information

Submitter's Name and Address	Submitter's Contact Person
TranS1 Incorporated 1800 Sir Tyler Drive, Suite 101 Wilmington, NC 28405	Robert L. Sheridan VP Regulatory and Clinical Phone: 910-509-3100 Fax: 910-509-3101 Email: rsheridan@trans1inc.com

Device Names

Proprietary Name:	TranS1® AxiaLIF™ System
Common/Usual Name:	Anterior spinal fixation device
Classification Name:	21 CFR 888.3060, Spinal Intervertebral Body Fixation Orthosis
Regulatory Classification:	Class II, product code KWQ

Predicate Device

The TranS1® AxiaLIF™ System, with a modified indication statement and the subject of this 510(k), is substantially equivalent to the TranS1 AxiaLIF™ System with its original indication statement, cleared under K040426 on December 17, 2004.

Device Description

The TranS1® AxiaLIF™ System is a multi-component system including titanium alloy implantable devices and instrumentation made of titanium alloy and stainless steel. This device includes instruments for creating a small pre-sacral, axial track to the L5 – S1 disc space. The track and the device's instruments are used for distracting the L5 – S1 vertebral bodies and inserting bone graft material into the disc space. The device also includes an anterior fixation rod that is implanted through the same track.

K050965

Intended Use and Indications for Use

TranS1® AxiaLIF™ System is intended to facilitate spinal fusion by providing axial access to the L5 – S1 disc space and axial stabilization of those vertebral bodies. The specific indication originally cleared under K040426 for the System and 3D Axial Rod™ was:

> The TranS1® AxiaLIF™ System is indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1 or 2), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The TranS1® AxiaLIF™ System is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 3 and 4), tumor or trauma. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5 – S1 in conjunction with legally marketed pedicle screw systems.

This 510(k) changes the last sentence of the indication statement to read as follows (the change appears in bold and in brackets):

> Its usage is limited to anterior supplemental fixation of the lumbar spine at L5 – S1 in conjunction with legally marketed [**facet and**] pedicle screw systems.

Technological Characteristics Comparisons

The technological characteristics of the TranS1® AxiaLIF™ System have not changed.

Summary of Testing

A significant amount of biomechanical and clinical testing of facet screws, and of facet screws in comparison to pedicle screws, appearing in the literature and as performed by TranS1®, establish that facet screw fixation will provided adequate posterior stabilization when used with the anterior stabilization of the AxiaLIF™ 3D Axial Rod™ (which is part of the AxiaLIF™ System).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2005

Mr. Robert L. Sheridan
Vice President for Regulatory and Clinical Affairs
Trans1 Incorporated
1800 Sir Tyler Drive, Suite 101
Wilmington, North Carolina 28405

Re: K050965
Trade/Device Name: TranS1® AxiaLIF™ System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: April 15, 2005
Received: April 19, 2005

Dear Mr. Sheridan:

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 (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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix IV

Indications for Use

510(k) Number (if known): K050965

Device Name: TranS1® AxiaLIF™ System

Indications for Use:

The TranS1® AxiaLIF™ System is indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1 or 2), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The TranS1® AxiaLIF™ is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 3 and 4), tumor or trauma. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5 – S1 in conjunction with legally marketed facet and pedicle screw systems.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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

510(k) Number K050965

page 1 of 1