K040426

DEC 17 2004

510 (k) Summary {As required by 21 CFR 807.92 (c)}

1. **Date of Summary**
November 30, 2004

2. **Submitter Information**

Submitter's Name and Address	Submitter's Contact Person
TranS1 Incorporated 1800 Sir Tyler Drive, Suite 101 Wilmington, NC 28409 Establishment Registration #: 3004578806	Cheryl Wagoner Quality Manager Phone: 910-509-3100 Fax: 910-509-3101 Email: cwagoner@trans1inc.com

3. **Device Names**

Proprietary Name:	TranS1 Axial Fixation 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

4. **Predicate Device**
The TranS1 Axial Fixation System is substantially equivalent to:

Manufacturer	Device	510 (k)	Cleared
Spineology Group, LLC	K-Centrum Anterior Spinal Fixation System	K002371	09/15/2000

5. **Device Description**
The TranS1 Axial Fixation System is a multi-component system including titanium alloy implantable devices and instrumentation made of titanium alloy and stainless steel. The following components are included: 3D Axial Fixation Threaded Rod/Screw, Axial Fixation Screw Plug, Axial Fixation Screw Driver, Material Inserter, and Axial Fixation Screw Plug Driver.

6. **Intended Use and Indications for Use**
The TranS1 Axial Fixation System is intended to provide anterior stabilization of the L5-S1 spinal segment as an adjunct to spinal fusion.

The TranS1 Axial Fixation 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 Axial Fixation 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Ms. Cheryl L. Wagoner
TranS1 Incorporated
1800 Sir Tyler Drive
Suite 101
Wilmington, North Carolina 28405

Re: K040426
Trade/Device Name: TranS1™ Axial Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: November 30, 2004
Received: December 1, 2004

Dear Ms. Wagoner:

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/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milleron

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): K040426

Device Name: TranS1™ Axial Fixation System

Indications for Use:

The TranS1™ Axial Fixation 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™ Axial Fixation 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.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K040426