K051856

SEP 26 2005

APPENDIX II: 510(K) SUMMARY

Prepared: July 07, 2005

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular 807.92, the following summary of information is provided:

Submitter Information

Submitter's Name and Address	Submitter's Contact Person
TranS1 Incorporated 1800 Sir Tyler Drive, Suite 101 Wilmington, NC 28409	Robert L. Sheridan Phone: 910-509-3100 Fax: 910-509-3101 Email: rsheridan@trans1inc.com

Device Names

Proprietary Name:	TranS1® Facet Screws
Common/Usual Name:	Posterior Facet Screw
Classification Name:	Unclassified Pre-Amendment Device
Product Code:	MRW
FDA Panel Code:	87 Orthopedics

Device Description

The TranS1® Facet Screws are made of medical grade titanium alloy conforming to such standards as ASTM F-136 and/or ISO 5832-3 or ASTM F-138 Stainless Steel.

Intended Use and Indications for Use

The TranS1® Facet Screws are to be used in conjunction with the TranS1® AxiaLIF™ System which includes the TranS1® 3D Axial Rod™, in order to create an anterior/posterior fixation construct as an aid to fusion.

The 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 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 facet and pedicle screw systems.

The facet screws may be implanted using one of two techniques: transfacetpedicular or translaminar. The screws are inserted bilaterally through the superior side of the facet, across the facet joint and into the pedicle. Alternatively, the facet screws may be cross inserted from the base of the spinous process into the opposite lamina and across the facet joint into the base of the lower vertebral transverse process.

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Substantial Equivalence

Documentation was provided to demonstrate that the TranS1® Facet Screws are substantially equivalent to the Medtronic Sofamor Danek Townley Transfacetpedicular Screw Fixation System (K003928) and the Sofamore Danek Transfacetpedicular Screw Fixation System (K953076). The TranS1 devices are substantially equivalent to the predicate devices in intended use, level of attachment, materials, labeling, sterilization, and technological characteristics. The range of sizes of the TranS1 devices is identical to, or a subset of, the range of sizes of the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 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: K051856
Trade/Device Name: TranS1® Facet Screws
Regulatory Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: MRW
Dated: July 7, 2005
Received: July 8, 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,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX VII: INDICATIONS FOR USE FORM

Indications for use form

510(k) Number (if known): K051856

Device Name: TranS1® Facet Screws

Indications for Use:

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Prescription Use ___X___ (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

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