

JAN 15 2004

K032891 1/2

## 510(k) Summary of Safety and Effectiveness

In Accordance with CFR 807.92 (April 26, 1992), the following information is submitted:

1. Name: TranS1, Inc.  
Address: 1800 Sir Tyler Drive  
Suite 101  
Wilmington, NC 28405  
  
Phone: 910 509-3100  
Fax: 910 509-3101  
  
Contact: W. Allen Putnam  
Date of Summary Preparation: January 12, 2004
2. Name of Device: TranS1 Trans-Sacral Spinal Access and Preparation Device  
Generic Name: Rigid Endoscope and Instrument Set
3. Predicate Devices:

AxiaMed, Inc., Trans-Sacral Spinal Access Device

Surgical Dynamics, Inc., 30K Working Channel Scope and instrument kit

Argus Medical Company Laparoscopic Discectomy Instrument System

Surgical Dynamics, Inc., Nucleotome Tissue Aspirator/Cutter

Surgical Dynamics, Inc., Nucleotome II Tissue Aspirator/cutter

Sofamor Danek Mfg., Inc., Danek Tissue Cutting and Removal System

United States Surgical, Auto Suture Spinal Elevator

Harrington Spinal Elevator

Karlin Technology, Inc., Cobb Spinal Elevator.

4. Device Description:

The TranS1 Trans-Sacral Spinal Access and Preparation Device is for minimally invasive access to the anterior lower spine and consists of the following components:

Guide Pin Introducer  
Guide Pins  
Dilators  
Dilators with sheath  
Guide Pin Steering Handle  
Twist Drills  
Cutters  
Brushs  
Exchange Rod  
Exchange Cannula  
Brush Delivery Sleeve  
Distraction Tool with driver  
Bone Graft Inserter  
Fibula Placement Tool

5. Indication for use:

The intended use of the TranS1 Trans-Sacral Spinal Access and Preparation Device is for minimally invasive access to the anterior portion of the lower spine for assisting in the treatment of degeneration of the lumbar disc, performing lumbar discectomy or for assistance in the performance of L5-S1 interbody fusion.

6. Technological Characteristics of the Device:

The TranS1 Trans-Sacral Spinal Access and Preparation Device is designed to gain a minimally invasive access tract to the anterior region of the lower spine and assist in the diagnosis and treatment of the area. This would enable procedures such as biopsy, lumbar fusion, vertebroplasty, etc. The access devices are of such length that access up to L5 is possible.



JAN 15 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

TranS1, Inc.  
c/o Mr. W. Allen Putnam  
RCQ Strategies  
6285 Chaska Road  
Excelsior, Minnesota 55331

Re: K032891

Trade/Device Name: TranS1 Trans-Sacral Spinal Access and Preparation Kit  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: II  
Product Code: HRX  
Dated: December 15, 2003  
Received: December 16, 2003

Dear Mr. Putnam:

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.

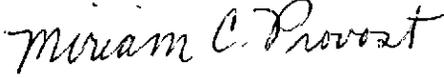
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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): K032891

Device Name: TranS1 Trans Sacral Spinal Access and Preparation Kit

### Indications For Use:

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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)

*Miriam C. Provost*  
\_\_\_\_\_  
Division Sign-Off  
Division of General, Restorative  
and Neurological Devices

Page 1 of \_\_\_\_\_

03/20/04 K032891