K092124

TranS1®

JAN 21 2010

Premarket Notification [510(K)] Summary
(per 21 CFR 807.92)

7/14/2009

Submitter:
TranS1, Inc.
411 Landmark Drive
Wilmington, NC 28412

Contact Person:
Cheryl L Wagoner
Quality and Regulatory Manager
910-332-1703 (phone)
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Proprietary Name: TranS1® AxiaLIF® 2L System

Classification: Spinal Intervertebral Body Fixation Orthosis
21 CFR 888.3060
Product Code: KWQ

Predicate Device: TranS1® AxiaLIF® II, K073643

Intended use:
TranS1® AxiaLIF® 2L System is intended to provide anterior stabilization of the L4-S1 spinal segments as an adjunct to spinal fusion. The AxiaLIF® 2L System is also intended 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 L4-S1 interbody fusion.

The AxiaLIF® 2L System is indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade 1), 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® 2L System is not intended to treat severe scoliosis, severe spondylolisthesis (Grades 2, 3 and 4), tumor, or trauma. The device is not meant to be used in patients with vertebral compression fractures or any other condition where the mechanical integrity of the vertebral body is compromised. Its usage is limited to anterior supplemental fixation of the lumbar spine at L4-S1 in conjunction with legally marketed facet or pedicle screw systems.

Device Description
The TranS1® AxiaLIF® 2L 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 tract to the L4-L5 and L5-S1 disc spaces. The track and the device's instruments are used for distracting the L4 – S1 vertebral bodies and inserting bone graft material into the disc space. The device also includes implantable anterior fixation rods that are implanted through the same tract.

Technological Characteristics and Substantial Equivalence
The technological characteristics of the TranS1® AxiaLIF® 2L System have not changed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 2 1 2010

TranS1, Inc.
% Ms. Cheryl L. Wagoner
Quality and Regulatory Manager
411 Landmark Drive
Wilmington, North Carolina 28412

Re: K092124
Trade/Device Name: TranS1® AxiaLIF® 2L System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 20, 2009
Received: November 23, 2009

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K092124

Device Name: TranS1® AxiaLIF® 2L System

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092124