K073514

Premarket Notification [510(K)] Summary

(per 21 CFR 807.92)

12 December 2007

JAN 1 1 2008

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

Contact Person:
William Jackson
Vice President, RA, CL, QA
910-332-1700 (phone)
910-233-7105 (fax)

Proprietary Name: TranS1® AxiaLIF® Fixation System

Classification:
Spinal Intervertebral Body Fixation Orthosis
21 CFR 888.3060
Product Code: KWQ
Arthroscope
21 CFR 888.1100
Product Code: HRX

Predicate Device: TranS1® Axial Fixation System, K050965 and K040426

Intended 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 or pedicle screw systems.

The intended use of the instrumentation kit 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.

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.

Technological Characteristics and Substantial Equivalence

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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TranS1, Inc.
% Mr. William Jackson
Vice President, RA, CL, QA
411 Landmark Drive
Wilmington, NC 28412

Re: K073514
Trade/Device Name: TranS1® AxiaLIF® System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ, HRX
Dated: December 12, 2007
Received: December 14, 2007

Dear Mr. Jackson:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K073514

Statement of Indications for Use

510(k) Number (if known):

Device Name: TranS1® AxiaLIF® Fixation 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 or pedicle screw systems.

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.

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 General, Restorative, and Neurological Devices

510(k) Number K073514

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