TranS1®

MAR 14 2011

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

February 7, 2011

Submitter:
TranS1, Inc.
301 Government Center Drive
Wilmington, NC 28403

Contact Person:
Cheryl L Wagoner
Director of Regulatory
910-332-1703 (phone)
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Proprietary Name: TranS1® AxiaLIF Plus

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

Predicate Device: AxiaLIF, AxiaLIF 2L+

Indications and Intended use:

TranS1 AxiaLIF® Plus System is intended to provide anterior stabilization of the L5-S1 or L4-S1 spinal segment (s) as an adjunct to spinal fusion. The AxiaLIF® Plus System is indicated for patients requiring fusion to treat pseudoarthrosis (unsuccessful previous fusion) spinal stenosis, spondylolisthesis (Grade 1 or 2 if single-level; Grade 1 if two-level), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 in conjunction with use of legally marketed facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF.

Device Description:

The TranS1® AxiaLIF® Plus 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 or L4-S1 disc space(s). The device's instruments are used for independently distracting the L5 – S1 or L4-S1 vertebral bodies and inserting bone graft material (DBM, autograft or autologous blood) into the disc space. The device includes an anterior fixation rod that is implanted through the same approach and is used to lock the construct together.

Technological Characteristics and Substantial Equivalence:

Documentation was provided to demonstrate that the TranS1® **AxiaLIF Plus** system is substantially equivalent to the predicates AxiaLIF (K073514) and AxiaLIF 2L+ (K092124). The TranS1 device is substantially equivalent to the predicate devices in intended use, level of attachment, materials, labeling, sterilization, and technological characteristics. These devices have the same intended use and indications and rely on the same fundamental scientific technology; therefore the Subject device is substantially equivalent to the Predicate devices.

The only significant difference from the predicate AxiaLIF 2L+ System is the use of an L5 Anchor and corresponding Fixation Rod to treat L5-S1 only instead of the longer solid L4-L5 Rod used to fixate L4-L5 in addition to L5-S1 in the case of a 2 level operation. The only additional instrumentation needed for the subject AxiaLIF 1L+ are unique 1 level L5 Dilator Trials used for the purpose of dilating and

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measuring for the correct implant sizes. These Dilator Trials are uniquely sized to the L5 anchors and provide the same functionality as the L4-L5 Dilator Trials of the predicate AxiaLIF 2L+ System. The AxiaLIF 1L+ implant is very similar to the predicate AxiaLIF 2L+ implant with the primary difference being an L5 Anchor that only engages the L5 vertebral body instead of a longer L4-L5 Rod that engages both the L4 and L5 vertebral bodies. The Distraction Rod of the subject device which spans the L5-S1 disc space is identical to the predicate Distraction Rod of the AxiaLIF 2L+ implant and the Fixation Rod has been slightly changed on the threaded end only to allow matching thread engagement with the appropriate L5 Anchor.

The table below compares the predicate devices and the subject device.

	Predicate AxiaLIF Single Level	Predicate AxiaLIF 2L+	Subject AxiaLIF Plus
Material	Titanium-6 Aluminum-4 Vanadium Alloy (Ti6Al4V), per ASTM F136-02	Titanium-6 Aluminum-4 Vanadium Alloy (Ti6Al4V), per ASTM F136-02	Identical
Overall Construct Lengths	40mm – 70mm	70mm – 110mm	Identical (inclusive of both predicates)
Diameter	L5 tip = 7.1mm; L5 base = 10.9mm; S1 section = 14.0mm	L4 tip = 7.1mm; L4 base = 12.9mm; L5 section = 15.5mm; S1= 15.5mm	Substantially equivalent
Shape	Tapered	Tapered	Identical
Fundamental Scientific Technology	Threaded Rod	Threaded Rod	Identical

Summary of Testing:

Mechanical, biomechanical, and system testing of the TranS1 AxiaLIF Plus system conforms to the ASTM 1717 standard as applicable to this device and is consistent with testing performed for the predicate devices. Testing performed for the subject device per this standard included Static Compression Bending, Static Torsion and Fatigue Compression Bending. All static and dynamic testing met or exceeded the requirements of as established by the test protocol and applicable ASTM standards. No new safety or effectiveness questions were raised as a result of the testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TranS1, Inc.
% Ms. Cheryl L. Wagoner
Director of Regulatory
301 Government Center Drive
Wilmington, North Carolina 28403

MAR 14 2011

Re: K102334
Trade/Device Name: TranS1® AxiaLIF Plus
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 08, 2011
Received: February 11, 2011

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: K102334

Device Name: TranS1® AxiaLIF Plus

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 K102334