K100210

TranS1®

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

August 16, 2010

AUG 2 6 2010

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

Contact Person:
Cheryl L Wagoner
Director of Regulatory
910-332-1703 (phone), 910-233-7105 (fax)

Proprietary Name: TranS1® Lateral Interbody Fusion

Classification: 888.3080: Intervertebral Fusion Device (MAX)

Predicate Device:

- Pioneer Surgical Technology: Pioneer Intervertebral Body Fusion System (K073177)
- Alphatec Spinte, Inc: Guided Lateral Interbody Fusion (GLIF) System (K090425)

Indications and Intended use:
The TranS1 Lateral Interbody Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The TranS1 Lateral Interbody Fusion Device is designed to be used with autogenous graft.

Device Description
The TranS1® Lateral Interbody Fusion Device is a radiolucent PEEK interbody fusion implant comprised of various heights and footprints to accommodate individual patient anatomy and graft material size. It also includes curved access instruments and disc preparation instruments. The TranS1® Lateral Interbody Fuson Device provides a lateral approach to the spine from a posterior angle while the patient is in a prone position. The lateral access technique allows a larger cage to be implanted similar to an anterior lumbar interbody fusion sized cage and the patient is already in the prone position which eliminates the need to flip the patient for supplemental posterior fixation. It is designed for use to provide structural stability in skeletally mature individuals.

Technological Characteristics and Substantial Equivalence
Documentation was provided to demonstrate that the TranS1® **Lateral Interbody Fusion Device is** substantially equivalent to the predicate Pioneer Intervetebral Body Fusion System (K073177) and Alphatec GLIF (K090425). 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

Summary of Testing
Mechanical testing for the TranS1 Lateral Interbody Fusion Device was performed per ASTM standards and included Static Axial Compression Strength (ASTM 2077-03), Static Subsidence (ASTM 2267-04), Static Push-out (ASTM Draft Standard F-04.25.02.02 and ASTM 2077-03) and Dynamic Axial Compression (Fatigue) (ASTM 2077-03). All static and dynamic testing met or exceeded the requirements 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
411 Landmark Drive
Wilmington, North Carolina 28412

AUG 2 6 2010

Re: K100210
Trade/Device Name: TranS1® Lateral Intervertebral Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 16, 2010
Received: August 18, 2010

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.

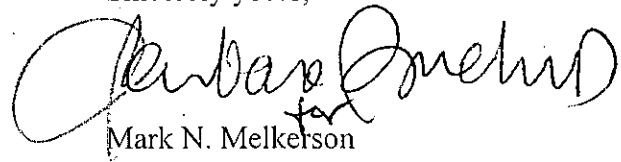
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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: K100210

AUG 2 6 2010

Device Name: TranS1® Lateral Interbody Fusion Device

Indications for Use:

The TranS1 Lateral Interbody Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The TranS1 Lateral Interbody Fusion Device is designed to be used with autogenous graft.

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 K100210

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