TranS1

MAR 11 2008

Response for K073515

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

Submitter: TranS1, Inc.
411 Landmark Drive
Wilmington, NC 28411

Contact Person: William Jackson
910-332-1700 (phone)
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Date Prepared: 6 March 2008

Proprietary Name: TranS1® Facet Screws

Common/Usual Name: Facet Screw Spinal Device

Classification Name: Unclassified

Product Code: MRW

Predicate Devices:

TranS1® Facet Screws, K051856

Medtronic Sofamor Danek Townley Transfacetpedicular Screw Fixation System, K003928

Sofamor Danek Transfacetpedicular Screw Fixation System, K953076

Intended use:

The TranS1® Facet Screws are to supplement legally marketed anterior fusion products in order to create an anterior/posterior fixation construct as an aid to fusion.

The facet screws may be implanted using one of two techniques: transfacetpedicular or translaminar. The screws are inserted bilaterally through the superior side of the facet, across the facet joint (usually) at a single level and into the pedicle. Alternatively, the facet screws may be cross inserted from the base of the spinous process into the opposite lamina and across the facet joint into the base of the lower vertebral transverse process. Bone graft must be used for both fixation methods.

For both techniques, the system is indicated for the posterior surgical treatment at C2-S1 (inclusive) spinal levels for the following: Spondylolisthesis; Spondylolysis; Pseudarthrosis or failed previous fusions which are symptomatic; Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facets with instability.

Device Description

The TranS1® Facet Screws are made of medical grade titanium alloy conforming to such standards as ASTM F-136 and/or ISO 5832-3 or ASTM F-138 Stainless Steel.

Technological Characteristics and Substantial Equivalence

Documentation was provided to demonstrate that the modified TranS1® Facet Screws are substantially equivalent to the original TranS1® Facet Screws (K051816) and the predicate Medtronic Sofamor Danek Townley Transfacetpedicular Screw Fixation System (K003928) and the Sofamor Danek Transfacetpedicular Screw Fixation System (K953076). The TranS1 devices are substantially equivalent to the predicate devices in intended use, level of attachment, materials, labeling, sterilization, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

TranS1, Inc.
% Mr. William Jackson
411 Landmark Drive
Wilmington, NC 28411

MAR 11 2008

Re: K073515
Trade/Device Name: TranS1® Facet Screws
Regulation Number: Unclassified
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: MRW
Dated: January 8, 2008
Received: January 13, 2008

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

Statement of Indications for Use

510(k) Number: K073515

Device Name: TranS1® Facet Screws

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)

Neil R.P. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073515