November 20, 2019

TranS1, Inc.
Ms. Kristen Allen
Director of Compliance and Regulatory Affairs
3804 Park Avenue, Suite C
Wilmington, North Carolina 28403

Re: K192792
Trade/Device Name: TranS1 AxiaLIF Plus System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 27, 2019
Received: September 30, 2019

Dear Ms. Allen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192792

Device Name
TranS1 AxiaLIF Plus System

Indications for Use *(Describe)*

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 legally marketed facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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TRAN1®

510(k) Summary

TranS1 AxiaLIF Plus System

Submitter: TranS1, Inc.
3804 Park Avenue, Suite C
Wilmington, NC 28403

Contact Person: Kristen Allen
Director of Compliance and Regulatory Affairs
910-612-4153 (P)
Kristen@trans1.com (e-mail)

Date Prepared: September 27, 2019

Trade Name: TranS1 AxiaLIF Plus System

Common Name: Appliance, Fixation, Spinal Intervertebral Body

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

Primary Predicate: TranS1 AxiaLIF Plus System (K102334)

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 distracting the L5 – S1 or L4-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.

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 legally marketed facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF.

Summary of Technological Characteristics:
The subject devices are substantially equivalent to the predicate device as well as other similar devices cleared by FDA for commercial distribution in the United States. The Subject Device was shown to have the same technological characteristics as its predicate devices through

comparison of characteristics including design, intended use, material composition, performance specifications and function.

Summary of Performance Testing:

The TranS1 AxiaLIF System was evaluated via an engineering analysis and V&V performance testing according to the predicate device. The results demonstrate the performance of the device is substantially equivalent to the predicate device.

Conclusion:
Based on the comparison to predicate device, the Subject Device has been shown to be substantially equivalent to the legally marketed predicate device.