September 25, 2019

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

Re: K191791
Trade/Device Name: TranS1 Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: September 10, 2019
Received: September 11, 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,

for Ronald P. Jean, PhD
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)*
K191791

Device Name
TranS1 Interbody Fusion System

Indications for Use *(Describe)*
The TranS1 Interbody Fusion System 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 I spondylolisthesis or retrolisthesis at the involved level(s). The TranS1 Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. These patients should have had six months of non-operative treatment. The TranS1 Interbody Fusion System is designed to be used with autograft and/or allograft comprised of cancellous and/or coritcocancellous bone graft, and a supplemental spinal fixation system that is cleared for use in the lumbar spine.

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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510(k) Summary

TranS1 Interbody Fusion 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 10, 2019

Trade Name: TranS1 Interbody Fusion System

Common Name: Intervertebral body fusion device

Device Product Code and Classification: Regulation Number: 21 CFR 888.3080
MAX, Class II, Intervertebral Fusion Device with Bone Graft, Lumbar

Primary Predicate: TranS1 Interbody Fusion Devices (K120991)

Additional Predicates: Life Spine Plateau Spacer System (K111569)
Amendia Interbody Fusion Device (K151310)
Choice Spine Lumbar Spacer System (K162103)
K2M Cascadia Interbody System (K172009)

Device Description:
The TranS1 Interbody Fusion System is used to provide structural stability and maintain disc space distraction in skeletally mature adults requiring intervertebral body fusion. The devices are designed to be used in conjunction with supplemental spinal fixation instrumentation. The subject devices are multiple component systems comprised of single-use implants designed to treat the lumbar spine.

The TranS1 Interbody Fusion System lumbar implants are fabricated from PEEK (ASTM F2026) with Tantalum (ASTM F560) x-ray markers. The TranS1 Interbody Fusion System implants are available in a range of sizes and shapes, and are designed to accommodate variations in surgical approach and patient anatomy. Each cage has a hollow center to allow placement of autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent expulsion.

Indications and Intended use:
The TranS1 Interbody Fusion System 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 I spondylolisthesis or

retrolisthesis at the involved level(s). The TranS1 Interbody Fusion System can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. These patients should have had six months of non-operative treatment. The TranS1 Interbody Fusion System is designed to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft, and a supplemental spinal fixation system that is cleared for use in the lumbar spine.

Summary of Technological Characteristics:
The subject devices are substantially equivalent to the predicate devices 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. Both the subject and predicate lumbar devices are interbody devices designed to contain graft material and facilitate fusion between two vertebral bodies in the lumbar region of the spine.

Summary of Performance Testing:
The worst-case device was tested in static compression, static torsion, static shear compression and dynamic compression (ASTM F2077), Subsidence (ASTM F2267) and Expulsion. An engineering analysis was presented to characterize all configurations of the Subject Device to confirm the worst-case device.

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