DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 7, 2017

SIATS, LLC
% Allison C. Komiyama, Ph.D., R.A.C.
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2834 Hawthorn Street
San Diego, California 92104

Re: K170855
Trade/Device Name: T-Rex Standalone ALIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: July 25, 2017
Received: July 26, 2017

Dear Dr. Komiyama:

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 contact the Division of Industry and Consumer Education (DICE) 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. 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 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 Industry and Consumer Education (DICE) 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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170855

Device Name
T-Rex Standalone ALIF

Indications for Use *(Describe)*

When used with the bone screws, the T-Rex Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K170855

DATE PREPARED
July 25, 2017

MANUFACTURER AND 510(k) OWNER
SIATS, LLC
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PROPRIETARY NAME OF SUBJECT DEVICE
T-Rex Standalone ALIF

COMMON NAME
Intervertebral Fusion Device with Integrated Fixation, Lumbar

DEVICE CLASSIFICATION
Intervertebral body fusion device
(21 CFR 888.3080, Product Code OVD Class II)

PREMARKET REVIEW
ODE/DOD/ASDB
Orthopedic Panel

INDICATIONS FOR USE
When used with the bone screws, the T-Rex Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

510(k) Summary

DEVICE DESCRIPTION

The T-Rex™ Standalone ALIF is a lumbar Intervertebral Body Fusion Device with integrated fixation made from HA Enhanced PEEK-OPTIMA (HAPEEK) incorporating titanium bone screws. The implants are available in various heights, widths, lengths, and angles of lordosis to accommodate patients' anatomy. The implants are provided sterile with surgical instruments provided non-sterile to facilitate implantation. Radiographic markers made of tantalum (ASTM F-560), are included in each implant to allow radiographic visualization.

PREDICATE DEVICE IDENTIFICATION

The T-Rex Standalone ALIF is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K141942	Midline II / Midline II / Centinel Spine Inc.	✓
K151785	Px HA PEEK IBF System / Innovasis, Inc.	
K162351	SeaSpine® Vu a•POD™ Prime NanoMetalene® / SeaSpine Orthopedics Corp.	
K170511	NeoFuse HA Enhanced PLIF/TLIF / HT Medical, LLC	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the T-Rex Standalone ALIF. The following tests were performed in order to demonstrate safety based on current industry standards:

- Static and dynamic compression and compression shear (per ASTM F2077)
- Subsidence (per ASTM F2267)
- Expulsion
- Push out test on the screws

The results of these tests indicate that the T-Rex Standalone ALIF is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

SIATS, LLC believes that the T-Rex Standalone ALIF is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has similar dimensions, similar materials and the same indications for use as the devices cleared in K141942 and K162351. It uses the same materials as the device cleared in K151785 and similar manufacturing processes as the device cleared in K170511. The subject device has a similar design and similar technological characteristics to the devices cleared in K141942 and K162351.

CONCLUSION

The T-Rex Standalone ALIF is considered substantially equivalent to the predicate devices based on the testing performed, the similar indications for use, and equivalent technological characteristics. Based on the testing performed, it can be concluded that the subject device is as safe and as effective compared to the predicate devices.