March 1, 2019

Clariance SAS
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K183259
Trade/Device Name: Idys™ TLIF TiVac
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: February 26, 2019
Received: February 26, 2019

Dear Ms. Hogan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -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: 06/30/2020
See PRA Statement on last page

510(k) Number *(if known)*
K183259

Device Name

Idys™ TLIF TiVac

Indications for Use *(Describe)*

The Idys™ TLIF TiVac cages are indicated for use with autologous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion, and are intended to be used with supplemental fixation instrumentation, which has been cleared by FDA 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.

510(k) SUMMARY
CLARIANCE's Idys™ TLIF TiVac
Intervertebral body fusion device with bone graft

Submitter's Name, Address, Telephone number, Contact person and Date prepared

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Contact Person: Willy VIVANZ, Chief Technology Officer

Date Prepared: November 21, 2018

Name of Device

Idys™ TLIF TiVac

Common or Usual Name

Lumbar Intervertebral Body Fusion Device with Bone Graft

Classification Name

Class II, 21 CFR §888.3080 - Intervertebral body fusion device, MAX

Predicate Devices

Idys™ TLIF Cage, CLARIANCE SAS (K131178): primary predicate

Lucent® Ti-BOND®, Spinal Elements (K150061): additional predicate (Titanium coating)

Purpose of the Traditional 510(k) notice

The Idys™ TLIF TiVac is a modification to the 510(k) approved Idys™ TLIF predicate (K131178). The modification consists of the addition of a plasma-sprayed, pure titanium coating compliant with ASTM F1580 on the superior and inferior surface of the device. The cages have equivalent design, shape, and dimensions as those already cleared under K131178 for the Idys™ TLIF cage predicate device.

Device Description

The Idys™ TLIF TiVac consists of interbody fusion devices intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the lumbar spine.

The Idys™ TLIF TiVac cages, which have various widths and heights, are designed for use as lumbar intervertebral body fusion devices. The device has a shape which restores the intervertebral height and lordosis. The device contains two slots to receive the autologous bone graft to promote the fusion process between the endplates. The device has to be used with autograft.

The superior and inferior surfaces of the implant are designed with “teeth” to help prevent the device from migrating once it is positioned. Additionally, the rough plasma-sprayed titanium surface interacts with the surface of the vertebral endplates and helps resist back out. The Idys™ TLIF TiVac cages are made of compliant ASTM F2026 polyetheretherketone (PEEK Optima®) with markers made of compliant ASTM F560 Tantalum and are coated with plasma-sprayed titanium compliant with ASTM F1580. Idys™ TLIF TiVac cages are positioned using a set of surgical instruments common for transforaminal lumbar approach. It is essential to insert implants with instrumentation specifically designed for this purpose. The cages are provided sterile and are for single use only.

Intended Use/Indications for Use

The Idys™ TLIF TiVac cages are indicated for use with autologous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion and are intended to be used with supplemental fixation instrumentation, which has been cleared by FDA for use in the lumbar spine.

Substantial Equivalence

The Idys™ TLIF TiVac cages and the predicate Idys™ TLIF (K131178) are designed for use as lumbar intervertebral body fusion devices. Both devices are available with equivalent range and configurations to accommodate patient anatomy.

The Idys™ TLIF TiVac and the Idys™ TLIF (K131178) cages feature a similar outer shape and design. Both devices are banana-shaped with a convex design and a bulleted nose. The shape is also similar to the Lucent® Ti-BOND® (K150061). The design features two slots to allow the incorporation of bone graft which is essential for promoting the fusion process. The superior and inferior surfaces of the Idys™ TLIF TiVac, the Idys™ TLIF (K131178) and Lucent® Ti-BOND® (K150061) have teeth to grip the surface of the vertebral endplates and help to resist expulsion.

The primary difference between the cleared Idys™ TLIF (K131178) and the subject device is the addition of the plasma-sprayed titanium coating on the superior and the inferior surface of the Idys™ TLIF TiVac cages. However, a similar coating has been cleared in the Lucent® Ti-BOND® (K150061).

Verification and validation steps performed following the addition of the titanium coating does not raise any new issues of safety or effectiveness compared to the cleared Idys™ TLIF cages (K131178).

Performance Data

Biocompatibility

The modified device has been demonstrated to be biocompatible in accordance with ISO 10993-1 Part 1.

Mechanical testing

Bench mechanical testing according to ASTM F2077 and ASTM F2267 were used to support the decision of substantial equivalence with Idys™ TLIF cages predicate device (K131178). Specifically, CLARIANCE performed static and dynamic axial compression testing, static and dynamic compression shear testing, subsidence testing, expulsion testing, static torsion testing, and wear testing (PEEK and titanium particles), all of which demonstrated the substantial equivalence of the system to legally marketed devices.

Mechanical bench testing of the pure titanium coating have been performed according to the FDA's guidance, *Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements*. Specifically, the following tests were performed: static tensile strength testing according to ASTM F1147, static shear strength according to ASTM F1044, shear fatigue strength according to ASTM F1160, abrasion resistance according to ASTM F1978-99, and coating porosity/thickness per ASTM F1854 with satisfactory results.

Conclusions

The Idys™ TLIF TiVac is equivalent to the Idys™ TLIF (K131178). The Idys™ TLIF TiVac has the same intended use and indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Idys™ TLIF TiVac and its predicate devices do not raise any new issues of safety or effectiveness compared to the predicate devices. Performance data demonstrate that the Idys™ TLIF TiVac is mechanically equivalent to its primary predicate.