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

June 6, 2019

Re: K191263
Trade/Device Name: Idys™ ALIF TiVac
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: May 10, 2019
Received: May 10, 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,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
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 on last page

510(k) Number *(if known)*
K191263

Device Name

Idys™ ALIF TiVac

Indications for Use *(Describe)*

The Idys™ ALIF (Anterior Lumbar Interbody Fusion) TiVac System is intended for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The Idys™ ALIF TiVac System should be used with the integrated fixation screws provided. The Idys™ ALIF TiVac System is intended to be used with autograft.

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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K191263
510(k) SUMMARY
CLARIANCE's Idys™ ALIF TiVac
Intervertebral Fusion Device With Integrated Fixation, Lumbar

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

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Contact Person: Willy VIVANZ, Chief Technology Officer

Date Prepared: May 28, 2019

Name of Device

Idys™ ALIF TiVac

Common or Usual Name

Intervertebral Fusion Device With Integrated Fixation, Lumbar

Classification Name

Class II, 21 CFR §888.3080 – Intervertebral body fusion device, OVD

Predicate Devices

Idys™ ALIF, CLARIANCE SAS (K172083): primary predicate

Idys™ TLIF TiVac, CLARIANCE SAS (K183259): additional predicate

Purpose of the Special 510(k) notice

The Idys™ ALIF TiVac is a modification to the 510(k) cleared Idys™ ALIF predicate (K172083). The modification consists of the addition of plasma-sprayed, pure titanium coating compliant with ASTM F1580 on the superior and inferior surface of the device. The same coating has been previously cleared in K183259. The cages have similar design, shape and dimensions as those already cleared under K172083 for the Idys™ ALIF predicate device.

Device Description

The Idys™ ALIF 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™ ALIF TiVac System is designed for use as a lumbar intervertebral body fusion device. The device is manufactured from medical grade polyetheretherketone (INVIBIO PEEK OPTIMA LT1) coated with titanium on its superior and inferior surfaces and is to be used with autograft.

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 superior and inferior surfaces of the implant coated with titanium are designed with teeth which interact with the surface of the vertebral endplates and helps in resisting back out. The Idys™ ALIF TiVac System is a standalone system intended to be used with plate and four bone screws, autogenous bone graft and requires no additional supplementary fixation. The Idys™ ALIF TiVac System cages are made of ASTM F2026 compliant polyetheretherketone (PEEK) coated with compliant ASTM F1580 titanium and, markers made of Tantalum according to ASTM F560, the plate and screws are made of ASTM F136 titanium alloy. It is essential to insert implants with instrumentation specifically designed for this purpose. The cages, plates and screws are provided sterile and are for single use only.

Indications for Use

The Idys™ ALIF (Anterior Lumbar Interbody Fusion) TiVac System is intended for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The Idys™ ALIF TiVac System should be used with the integrated fixation screws provided. The Idys™ ALIF TiVac System is intended to be used with autograft.

Substantial Equivalence

The Idys™ ALIF TiVac and the predicate Idys™ ALIF (K172083) 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™ ALIF TiVac and the Idys™ ALIF (K172083) feature a similar outer shape and design. 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™ ALIF TiVac and the Idys™ ALIF (K172083) have teeth to grip the surface of the vertebral endplates and help to resist expulsion.

The primary difference between the cleared Idys™ ALIF (K172083) and the subject device is the addition of the plasma-sprayed titanium coating on the superior and the inferior surface of the Idys™ ALIF TiVac cages. However, the same coating has been cleared in CLARIANCE Idys™ TLIF TiVac (K183259).

Verification and Validation steps performed following the addition of the titanium coating demonstrate that the modification does not raise any new issues of safety or effectiveness compared to the cleared Idys™ ALIF (K172083).

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 was used to support the decision of substantial equivalence compared to the Idys™ ALIF predicate device (K172083). 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). The results of these studies were determined to be substantially equivalent to legally marketed devices.

Mechanical bench testing of the pure titanium coating was 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™ ALIF TiVac is as safe and effective as the Idys™ ALIF (K172083). The Idys™ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Idys™ ALIF TiVac and its predicate device do not raise any new issues of safety or effectiveness. Performance data demonstrate that the Idys™ ALIF TiVac is as safe and effective as its predicate. Thus, the Idys™ ALIF TiVac is substantially equivalent.