November 4, 2019

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

Re: K192168
Trade/Device Name: Idys® ALIF ZP 3DTi
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: August 9, 2019
Received: August 9, 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/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, 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 on last page

510(k) Number *(if known)*
K192168

Device Name

Idys® ALIF ZP 3DTi

Indications for Use *(Describe)*

The Idys® ALIF ZP 3DTi devices (Anterior Lumbar Interbody Fusion) are intended for use in patients with degenerative disc disease (DDD) at one (1) or (2) contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as back pain in 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 ZP 3DTi cages should be used with the integrated fixation screws provided.

The Idys® ALIF ZP 3DTi cages are 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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510(k) SUMMARY
CLARIANCE's Idys® ALIF ZP 3DTi
Intervertebral body fusion device

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

CLARIANCE, SAS
18 rue Robespierre
62217 Beaurains, France

Phone: + 33 (0)3 21 16 12 15
Facsimile: + 33 (0)3 21 15 50 73

Contact Person: Fadwa Bahr, Quality and Regulatory Affairs Manager

Date Prepared: August 9, 2019

Name of Device

Idys® ALIF ZP 3DTi

Common or Usual Name

Lumbar Intervertebral Body Fusion Device with Integrated Fixation

Classification Name

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

Predicate Devices

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

Idys® TLIF 3DTi, CLARIANCE SAS (K172465): additional predicate

Purpose of the 510(k) Notice

The Idys® ALIF ZP 3DTi device is a modification of the 510(k) approved Idys® ALIF predicate (K172083). The modification consists of a change of raw materials, Ti-6Al-4V ELI Titanium alloy replaces PEEK used in Idys® ALIF. The cages have similar design, shape and dimensions as those already cleared under K172083 for the Idys® ALIF cages predicate device.

Device Description

The Idys® ALIF ZP 3DTi 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 ZP 3DTi cages, which have various widths and heights, are designed for use as lumbar intervertebral body fusion devices. The device shape 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 Idys® ALIF ZP 3DTi cage is manufactured from medical grade Ti-6Al-4V ELI Titanium alloy compliant with ASTM F3001 and ASTM F136 and is used with autograft. The screws are made from Ti-6Al-4V ELI per ASTM F136 and are anodized in different colors, according to their length. Idys® ALIF ZP 3DTi cages are positioned using a set of surgical instruments common for anterior 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® ALIF ZP 3DTi devices (Anterior Lumbar Interbody Fusion) are intended for use in patients with degenerative disc disease (DDD) at one (1) or (2) contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as back pain in 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 ZP 3DTi cages should be used with the integrated fixation screws provided.

The Idys® ALIF ZP 3DTi cages are intended to be used with autograft.

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® ALIF cages and Idys® TLIF 3DTi predicate devices (K172083 and K172465, respectively). 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 (titanium particles), all of which demonstrated the substantial equivalence of the system to legally marketed devices.

Conclusions

The Idys® ALIF ZP 3DTi is as safe and effective as the Idys® ALIF (K172083) and Idys® TLIF 3DTi (K1724665). The Idys® ALIF ZP 3DTi 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 ZP 3DTi and its predicate devices do not raise any different questions of safety or effectiveness. Performance data demonstrate that the Idys® ALIF ZP 3DTi is as safe and as effective as its predicates. Thus, the Idys® ALIF ZP 3DTi is substantially equivalent.