October 12, 2021

CLARIANCE, SAS
% Janice Hogan, J.D.
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K212562
Trade/Device Name: Idys®-C ZP 3DTi
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: August 13, 2021
Received: August 13, 2021

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,

Brent Showalter, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212562

Device Name
Idys® C ZP 3DTi

Indications for Use *(Describe)*
The Idys®-C ZP 3DTi device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one (1) or more levels from C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had at least six (6) weeks of non-operative treatment. The Idys®-C ZP 3DTi device must be used with the integrated fixation screws provided. The Idys®-C ZP 3DTi device must be filled with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. The Idys®-C ZP 3DTi device is to be implanted via an open, anterior approach.

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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K212562

510(k) SUMMARY

CLARIANCE's Idys® C ZP 3DTi

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

CLARIANCE, SAS
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F-62217 Beaurains, France
Phone: +33 (0)3 21 16 12 15
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Contact Person: Mélody La Porte, Regulatory Affairs Specialist
Date Prepared: October 6, 2021

Name of Device and Name/Address of Sponsor

CLARIANCE, Idys® C ZP 3DTi

Common or Usual Name

Intervertebral Fusion Device with Integrated Fixation, Cervical

Classification Name

Class II, 21 CFR § 888.3080 - Intervertebral Fusion Device, OVE

Predicate Devices

Primary: Idys™-C, CLARIANCE SAS (K130853): (Instruments mechanical performances, device mechanical performances, packaging and sterilization)

Additional: Vault-C Standalone Cervical Interbody Fusion System, Spinal USA, Inc. (K132029)

Additional: Idys®-ALIF ZP 3DTi, CLARIANCE SAS (K200920) (screws, manufacturing, cleaning and raw materials)

Intended Use / Indications for Use

The Idys®-C ZP 3DTi device is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one (1) or more levels from C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had at least six (6) weeks of non-operative treatment. The Idys®-C ZP 3DTi device must be used with the integrated fixation screws provided. The Idys®-C ZP 3DTi device must be filled with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. The Idys®-C ZP 3DTi device is to be implanted via an open, anterior approach.

Device Description

The Idys® C ZP 3DTi is designed for use as a cervical intervertebral body fusion device. The device is manufactured from medical grade Titanium alloy and must be filled with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. The device has a shape which restores the intervertebral height and lordosis. The device contains one (1) slot to receive the bone graft to promote the fusion process between the endplates. The Idys® C ZP 3DTi is a standalone system intended to be used with two (2) bone screws, bone graft and requires no additional supplementary fixation. The Idys® C ZP 3DTi cages are made of compliant ASTM F3001 and ASTM F136 Titanium alloy and screws are made of ASTM F136 Titanium alloy.

Performance Data

Biocompatibility

As there have been no changes to the manufacturing methods or patient contacting materials, no new biocompatibility testing was required to establish equivalence. Confirmatory testing per ISO 10993-5 and ISO 10993-11 had been performed.

Sterility and Cleaning

Sterilization validation per ISO 11137 has been successfully completed. Cleaning validation per ISO 19227 has shown acceptable limits of residues.

Mechanical Testing

Mechanical testing according to ASTM F2077 and ASTM F2267 were used to support substantial equivalence to Idys™ C (K130853). Specifically, CLARIANCE performed static and dynamic axial compression testing, static and dynamic compression shear testing, subsidence testing, expulsion testing, static torsion testing, all of which demonstrated the substantial equivalence of the system to legally marketed devices.

Substantial Equivalence

The Idys® C ZP 3DTi is substantially equivalent to the Idys™-C (K130853) and Vault-C Standalone Cervical Interbody Fusion System (K132029). The Idys® C ZP 3DTi has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the Idys® C ZP 3DTi and its predicate devices do not raise any new questions of safety or effectiveness. In addition, performance data demonstrate that the Idys® C ZP 3DTi is as safe and effective as its predicate devices. Thus, the Idys® C ZP 3DTi is substantially equivalent.