December 15, 2017

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

Re: K172465
Trade/Device Name: Idys™ TLIF 3DTi cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 17, 2017
Received: November 17, 2017

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. 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.

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.

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,

Mark N. Melkerson -S

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 below

510(k) Number *(if known)*

K172465

Device Name

Idys™ TLIF 3DTi

Indications for Use *(Describe)*

The Idys™ TLIF 3DTi cages are indicated for use with autogenous 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 implants may be implanted via a posterior and/or transforaminal approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared 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.

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510(k) SUMMARY

CLARIANCE's Idys™ TLIF 3DTi

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

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Contact Person: Pascal Rokegem, Chief Technology Officer

Date: December 6, 2017

Name of Device and Name

Idys™ TLIF 3DTi

Common or Usual Name

Lumbar Intervertebral Body Fusion Device

Classification Name

888.3080 - Intervertebral body fusion

Product Code

MAX

Predicate Devices

CLARIANCE, Idys TLIF Cage, K131178 (primary)

K2M, CASCADIA TL, K150481 (additional)

Intended Use / Indications for Use

The Idys™ TLIF 3DTi cages are indicated for use with autogenous 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 implants may be implanted via a posterior and/or

transforaminal approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Device Description

The Idys™ TLIF 3DTi cages, which have various widths and heights, are designed for use as a lumbar intervertebral body fusion device. The device has to be used with autograft. The device has a shape which restores the intervertebral height and lordosis. The device contains a slot to receive the autologous bone graft to promote the fusion process between the endplates. The Idys™ TLIF 3DTi cages are made of compliant ASTM F136 Titanium alloy. The device is manufactured using an additive manufacturing process to result in a porous material with tightly defined structure. It is essential to insert implants with instrumentation specifically designed for this purpose.

Comparison of Technological Characteristics

The Idys™ TLIF 3DTi cages and the predicate Idys™ TLIF (K131178) are designed for use as lumbar intervertebral body fusion devices. All devices are composed of cages or "interbody spacers" available with various configurations to accommodate patient's anatomy.

The Idys™ TLIF 3DTi 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 CASCADIA™ TL (K150481). The design features slots to allow the incorporation of bone graft which is essential to promoting the fusion process. The difference in the number of slots for autograft between the Idys™ TLIF 3DTi and Idys™ TLIF predicate (K131178) do not raise new or different issues of safety and effectiveness since the volume available for autograft is equivalent. Unlike the Idys™ TLIF cages (K131178), each of the superior and inferior surfaces of the Idys™ TLIF 3DTi cages devices do not have teeth since the roughness of the porous structure is sufficient to grip the surface of the vertebral endplates and help resist expulsion. Although there are no teeth on the superior and inferior surfaces, the expulsion testing has demonstrated adequate resistance to expulsion.

In terms of configurations, the Idys™ TLIF 3DTi cages are similar to those of the cleared Idys™ predicate (K131178). The Idys™ TLIF 3DTi cages are available with two footprints with different heights ranges and no lordotic angles.

The structure of both Idys™ TLIF 3DTi and CASCADIA™ TL (K150481) is made of porous titanium with rough surfaces in order to achieve biological fixation. Mechanical testing has shown that this structure does not have an adverse impact on the mechanical performance of the the Idys™ TLIF 3DTi cages.

Performance Data

Performance testing was conducted according to ASTM F2077 and ASTM F2267. 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. The results of these studies were determined to be substantially equivalent to legally marketed devices.

Conclusion

The Idys™ TLIF 3DTi is as safe and effective as the Idys™ TLIF (K131178) and CASCADIA™ TL (K150481). The Idys™ TLIF 3DTi has the same intended use, similar indications, principles of operation, and technological characteristics as the Idys™ TLIF (K131178) and the CASCADIA™ TL (K150481). Bench testing has shown equivalent performance. Thus, the Idys™ TLIF 3DTi is substantially equivalent.