November 8, 2017

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

Re: K172083
Trade/Device Name: Idys™ ALIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: October 12, 2017
Received: October 12, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Katherine D. Kavlock -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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K172083

Device Name

Idys™ ALIF System

Indications for Use *(Describe)*

The Idys™ ALIF (Anterior Lumbar Integrated Fusion) 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 System should be used with the integrated fixation screws provided.

The Idys™ ALIF System is intended to be used with autograft.

Type of Use *(Select one or both, as applicable)*

X 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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K172083

510(k) SUMMARY

CLARIANCE's Idys™ ALIF System

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

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Contact Person: Pascal Rokegem, Chief Technology Officer

Date Prepared: October 12, 2017

Name of Device and Name

Idys™ ALIF System

Common or Usual Name

Lumbar Intervertebral Body Fusion Device

Classification Name

888.3080 - Intervertebral body fusion

Product Code

OVD

Predicate Devices

Medtronic, DIVERGENCE-L, K150135 (primary)

CLARIANCE, Idys LIF Cage, K131178 (additional)

Intended Use / Indications for Use

The Idys™ ALIF (Anterior Lumbar Fusion Integrated Fusion) 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 to S1). DDDis 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 six (6) months of non-operative treatment. The Idys™ ALIF System should be used with the integrated fixation screws provided. The Idys™ ALIF System is intended to be used with autograft.

Device Description

The Idys™ ALIF System is manufactured from medical grade polyetheretherketone (INVIBIO PEEK OPTIMA LT1) 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 are designed with teeth which interact with the surface of the vertebral endplates and helps resist back out.

The Idys™ ALIF System is connected to a plate with four screws for a standalone implantation. The Idys™-ALIF System are made of ASTM F2026 compliant polyetheretherketone (PEEK) and markers made of Tantalum according to ASTM F560, the plate and screws are made of ASTM F136 titanium alloy.

Comparison of Technological Characteristics

The Idys™ ALIF System and the predicate DIVERGENCE-L™ are designed for use as lumbar intervertebral body fusion devices. All devices are composed of PEEK cages or “interbody spacers” available with various configurations to accommodate patient anatomy. These cages incorporate Tantalum radiographic markers to allow the verification of the cage position during surgery and post-operatively.

The Idys™ ALIF System and the DIVERGENCE-L™ cages feature a similar outer shape and design. Both devices are rectangular with rounded corners, and feature open spaces to allow the incorporation of bone graft which is essential to promote the fusion process. Each of the superior and inferior surfaces of the Idys™ ALIF System and the DIVERGENCE-L™ devices are designed with teeth to grip the surface of the vertebral endplates and help in resisting expulsion.

In terms of configurations, the Idys™ ALIF System cages are very similar to those of the cleared DIVERGENCE-L™ predicate (K150135). The Idys™ ALIF System cages are available with four footprints with different heights ranges and lordotic angles. The differences in the dimensions of the Idys™ ALIF System cages compared to those cleared for the DIVERGENCE-L™ predicate do not raise new issues of safety and effectiveness because the available heights, lordotic options and footprints fall within the range of dimensions offered by the predicate device. Mechanical testing has shown that the addition of a smaller footprint does not have an adverse impact on the mechanical performance of the Idys™ ALIF System cages .

The shape and size offerings differ slightly from the Idys LIF (K131178), which has a flatter and longer shape, but is made from the same materials. The differences in shape do not raise different types of safety or effectiveness questions and mechanical testing shows at least equivalent performance.

The plates intended to be used with the Idys™ ALIF System have similar dimensions as compared to those cleared for DIVERGENCE-L™ predicate device (K150135). The width and the profile of the predicate DIVERGENCE-L is greater than the Idys™ ALIF System plate, but these differences do not raise new or different issues of safety and effectiveness and are supported by testing.

The bone screws proposed with the Idys™ ALIF System have similar dimensions compared to those cleared for the DIVERGENCE-L™ predicate device (K150135) in terms of lengths and diameters. Additionally, the screws of the Idys™ ALIF System are made from the same ASTM F136 medical grade material titanium alloy (Ti6Al4V ELI) as the one used for the cleared DIVERGENCE-L™ predicate screws.

Performance Data

Performance testing was conducted per Modified ASTM F2077 for inclusion of the plate and screw in the testing protocol and ASTM F2267. Specifically, CLARIANCE performed static and dynamic axial compression testing, static and dynamic compression shear testing, subsidence testing, expulsion testing, torsion testing, and wear particle characterization. The results of these studies were determined to be substantially equivalent to legally marketed devices.

The subject device also complies with 11137-1, 11137-2, 11607-1 and 11607-2.

Conclusion

The Idys™ ALIF System is as safe and effective as the Divergence-L (K150135) and Idys LIF (K131178). The Idys™ ALIF System has the same intended uses, similar indications, principles of operation, and technological characteristics as the Divergence-L and the Idys LIF. Bench testing has shown equivalent performance. Thus, the Idys™ ALIF System is substantially equivalent.