April 1, 2021

CLARIANCE, SAS
℅ Janice M. Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K202032
Trade/Device Name: Idys® LLIF 3DTi
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 9, 2021
Received: March 9, 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 L. 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 on last page

510(k) Number *(if known)*
K202032

Device Name
Idys® LLIF 3DTi

Indications for Use

The Idys® LLIF 3DTi system is intended for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous level(s) 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 level(s). These patients should be skeletally mature and have had at least six (6) months of non-operative treatment.

The Idys® LLIF 3DTi system is intended to be used with bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and with cleared supplemental fixation in addition to the integrated plate and screws.

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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K202032

510(k) SUMMARY

CLARIANCE's Idys® LLIF 3DTi

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

CLARIANCE

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Contact Person: Fadwa Bahr, Quality and Regulatory Affairs Manager

Date Prepared: March 9, 2021

Name of Device and Name/Address of Sponsor

CLARIANCE, Idys® LLIF 3DTi

Common or Usual Name

Lumbar Intervertebral Body Fusion Device with Bone Graft

Classification Name

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

Predicate Devices

Idys® ALIF ZP 3DTi, CLARIANCE SAS (K200920): primary predicate (screws, manufacturing process, cleaning, sterilization and packaging validation)

Idys® ALIF System, CLARIANCE SAS (K172083): additional predicate (system, instruments mechanical performance)

Idys® PLIF CLARIANCE SAS (K131178): additional predicate (mechanical performance)

InFill® Interbody Fusion Devices, Pinnacle Spine Group, LLC (K152259) (cage size and lateral approach reference device)

SIRION Lateral Lumbar Interbody Fusion System, Astura Medical, LLC (K192006) (cage size and lateral approach reference device)

Intended Use / Indications for Use

The Idys® LLIF 3DTi system is intended for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous level(s) 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 level(s). These patients should be skeletally mature and have had at least six (6) months of non-operative treatment.

The Idys® LLIF 3DTi system is intended to be used with bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone and with cleared supplemental fixation in addition to the integrated plate and screws.

Technological Characteristics

The Idys® LLIF 3DTi is designed for use as a lumbar intervertebral body fusion system. The device is manufactured from medical grade Titanium alloy using an additive manufacturing method and is to be used with bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. The cage has a shape which restores the intervertebral height and lordosis. The cage contains two (2) slots to receive the bone graft to promote the fusion process between the endplates. The Idys® LLIF 3DTi is a system intended to be used with a plate and two (2) bone screws, bone graft and supplemental fixation that has been authorized for surgical use in the lumbar spine. The Idys® LLIF 3DTi components are made of compliant ASTM F136 Titanium alloy.

Performance Data

Biocompatibility

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

Sterility and Cleaning

Sterilization validation per ISO 11737 and ISO 11137 has been successfully completed. Cleaning validation has shown acceptable limits of residues.

Mechanical Testing

Mechanical testing according to ASTM F2077 and ASTM F2267 were used to support substantial equivalence with Idys® ALIF System and Idys® PLIF, (cleared respectively in K172083 and K131178). Specifically, CLARIANCE performed static and dynamic axial compression testing, static and dynamic compression shear testing, subsidence testing, expulsion testing, static torsion testing, and particle characterization, all of which demonstrated the substantial equivalence of the system to legally marketed devices.

Substantial Equivalence

The Idys® LLIF 3DTi system and its predicates 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 and are to be used with the provided plates and screws and supplemental fixation.

The Idys® LLIF 3DTi and Idys® ALIF ZP 3DTi (K200920) cages are made using the same additive manufacturing method using titanium alloy per ASTM F3001 and results in the same, porous structure. In contrast, the Idys® ALIF System (K172083), Idys® PLIF (K131178), InFill® Interbody Fusion Devices (K152259) and SIRION Lateral Lumbar Interbody Fusion cages are made of PEEK OPTIMA LT1® per ASTM 2026 (while the SIRON can also contain HA). Differences in cage material do not raise difference questions, as both devices raise the same questions regarding biocompatibility and mechanical performance. Both Titanium Alloy Ti6Al4V ELI and PEEK are well-known materials that have been used for many years, and which are standardized by ISO/ASTM as implantable grade of materials. Mechanical testing has shown that this structure does not have an adverse impact on the mechanical performance of the Idys® LLIF 3DTi system. The use of porous lattice allows the 3DTi cages to have similar stiffness than cages made of PEEK, avoiding stress-shielding and providing a scaffold for bone fusion.

The Idys® LLIF 3DTi cages, the SIRION LLIF System Devices (K192006) and the InFill® Interbody Fusion Devices (K152259) cages are inserted using a lateral approach and, accordingly, feature a similar outer shape and design. All three devices are long cages with a bulleted nose and contain slots to allow the incorporation of bone graft which is essential to promoting the fusion process. The difference in the number of slots for bone graft between the Idys® LLIF 3DTi, InFill® V2 Lateral Interbody Fusion (K152259) and SIRION Lateral Lumbar Interbody Fusion System (K192006) predicates do not raise new or different issues of safety and effectiveness since the volume available for bone graft is equivalent. Unlike the InFill® V2 Lateral Interbody Fusion (K152259) and SIRION Lateral Lumbar Interbody Fusion System (K192006) predicates, each of the superior and inferior surfaces of the Idys® LLIF 3DTi cages 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® LLIF 3DTi system are similar to those of the cleared InFill® V2 Lateral Interbody Fusion predicate (K152259). Additionally, all Idys® LLIF 3DTi cage heights are within SIRION (K192006) range. The Idys® LLIF 3DTi cages are available with various footprints with different heights ranges and lordotic angles.

Conclusions

The Idys® LLIF 3DTi is substantially equivalent to Idys® ALIF ZP 3DTi (K200920). The Idys® LLIF 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® LLIF 3DTi and its predicate device do not raise any new issues of safety or effectiveness. Performance data demonstrate that the Idys® LLIF 3DTi is as safe and effective

as its predicate. Thus, the Idys® LLIF 3DTi is substantially equivalent.