



December 31, 2024

Clariance
Mr. Quang Tran
Clinical & Quality & Regulatory Affairs VP
18, Rue Robespierre
Beaurains, FR 62217
France

Re: K243670
Trade/Device Name: Idys® LIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 30, 2024
Received: November 27, 2024

Dear Mr. Quang Tran:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

EILEEN CADEL

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for 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

Indications for Use

Submission Number (if known)

K243670

Device Name

Idys® LIF

Indications for Use (Describe)

The Idys® PLIF cage is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L3 to S1. The Idys® PTLIF, Idys® TLIF 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 by the FDA 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® LIF

Submitter

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Contact Person: Quang TRAN, Quality Assurance, Regulatory Affairs and Clinical VP

Date Prepared: October 30th, 2024

Name of Device: Idys® LIF

Common or Usual Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Classification Name: Intervertebral body fusion device, 21 CFR § 888.3080

Regulatory Class: Class II

Product Code: MAX

Predicate Device: Idys® LIF Cages, Clariance (K131178)

Device Description

The Idys®-LIF cages, which have various widths and heights, are designed for use as a lumbar interbody fusion device. The device has to be used with autograft. The device has a shape which restores the intervertebral height and lordosis. The device can contain one or more 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 a rough surface which interact with the surface of the vertebral endplates and help in resisting back out. The Idys®-LIF cages are made of compliant ASTM F2026 polyetheretherketone (PEEK) with markers made of compliant ASTM F560 Tantalum for PLIF and PTLIF, made of compliant ASTM F560 Tantalum and made of compliant ASTM F136 Titanium alloy for TLIF. It is essential to insert implants with instrumentation specifically designed for this purpose.

Intended Use / Indications for Use

The Idys[®] PLIF cage is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L3 to S1. The Idys[®] PTLIF, Idys[®] TLIF 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 by the FDA for use in the lumbar spine.

Summary of Technological Characteristics

With the exception of a non-sterile state, need to be sterilized prior to use and dedicated trays equivalent to the state of the art for transportation, storage and sterilization of orthopedic devices, the modified Idys[®] LIF possess the same technological characteristics as the predicate devices. The fundamental scientific technology of the subject devices remains unchanged.

Performance Data

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

Conclusions

With the exception of removed level L2 - L3 indications for Idys[®] PTLIF only, the Idys[®] LIF indications for use is similar to the cleared Idys[®] LIF Cages (K131178). The Idys[®] LIF has similar intended use and principles of operation and similar technological characteristics as the cleared Idys[®] LIF Cages (K131178). In addition, the minor technological differences between the Idys[®] LIF and its predicate devices, which is a non-sterile state and dedicated trays equivalent to the state of the art for transportation, storage and sterilization of orthopedic devices, raises no new issues of safety or effectiveness. Performance data demonstrate that Idys[®] LIF is as safe and effective as the cleared Idys[®] LIF Cages (K131178). Thus, the subject Idys[®] LIF is substantially equivalent to the cleared Idys[®] LIF Cages (K131178).