March 22, 2024

Clariance
Magalie Hennequin
Clinical & Quality & Regulatory Affairs Director
18, rue Robespierre
Beaurains, 62217
France

Re: K240715
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: March 13, 2024
Received: March 15, 2024

Dear Magalie Hennequin:

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.

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,

Brent Showalter -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240715

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 and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone graft. 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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510(K) SUMMARY

CLARIANCE's Modified IDYS® C ZP 3DTi

Submitter

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Contact Person: Magalie HENNEQUIN, Clinical & Quality & Regulatory Affairs Director

Date Prepared: March 13th, 2024

Name of Device: Idys® C ZP 3DTi

Common or Usual Name: Intervertebral Fusion Device with Integrated Fixation, Cervical

Classification Name: Intervertebral Body Fusion Device, 21 CFR 888.3080

Regulatory Class: Class II

Product Code: OVE

Primary Predicate: IDYS® C ZP 3DTi, CLARIANCE (K212562)

Additional Predicate: Vault C Standalone Cervical Interbody Fusion System (K132029)

Device Description

The Idys® C ZP 3DTi device consists of a cervical intervertebral body fusion system. The device is manufactured from medical grade Titanium alloy and is to be used with autograft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone graft. 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 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. It is essential to insert implants with instrumentation specifically designed for this purpose.

The Idys® C ZP 3DTi device consists of cages and screws, as well as associated surgical instruments.

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 and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone graft. The Idys®-C ZP 3DTi device is to be implanted via an open, anterior approach.

Summary of Technological Characteristics

The subject and predicate (K212562) devices have nearly identical technological characteristics and the minor differences in screw geometry do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicate:

- Same material (ASTM F136 Titanium alloy)
- Same diameters (3.5mm and 4.0mm)
- Same manufacturing process.

Performance Data

The subject Idys® C ZP 3DTi screws have been tested in the following test:

- Axial pullout load (ASTM F543)

The results of this non-clinical testing show that the subject Idys® C ZP 3DTi is substantially equivalent to legally marketed predicate device.

Conclusions

The modified Idys® C ZP 3DTi has the same intended use and indications, principles of operation and similar technological characteristics as the cleared Idys® C ZP 3DTi (K212562). In addition, the minor technological differences between the modified Idys® C ZP 3DTi and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the modified Idys® C ZP 3DTi is as safe and effective as the cleared Idys® C ZP 3DTi (K212562). Thus, the subject Idys® C ZP 3DTi is substantially equivalent to the cleared Idys® C ZP 3DTi (K212562).