Clariance
% Magalie Hennequin
Quality & Regulatory Affairs & Clinical Director
Clariance Inc.
42547 Farrington Street
Dallas, Texas 75207

July 24, 2024

Re: K241863
Trade/Device Name: Erisma® Lp Spinal Fixation System; Erisma® LP MIS
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: June 24, 2024
Received: June 27, 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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2024.07.24 08:30:16 -04'00'

for

Colin O'Neill, M.B.E.
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 below.

510(k) Number *(if known)*
K241863

Device Name
Erisma® Lp Spinal Fixation System;
Erisma® LP MIS

Indications for Use *(Describe)*
When used as a pedicle screw fixation system of the non- cervical posterior spine in skeletally mature patients using allograft and/or autograft, the Erisma® LP Spinal System is indicated as an adjunct to fusion for the following indications: Degenerative Disc Disease (Define as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); degenerative spondylolisthesis with objective evidence of neurologic impairment; severe spondylolisthesis (grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; fracture; dislocation; scoliosis; kyphosis; spinal tumor; failed previous fusion (pseudarthrosis)

The Erisma® LP MIS components are intended for percutaneous, posterior, non-cervical pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications:
• Degenerative disc disease (Define as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
• Degenerative spondylolisthesis with objective evidence of neurologic impairment,
• Severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint,
• Fracture,
• Dislocation,
• Scoliosis,
• Kyphosis,
• Spinal tumor,
• Failed previous fusion (pseudarthrosis).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Erisma® LP Spinal Fixation System
Erisma® LP MIS

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

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Contact Person: Magalie HENNEQUIN, Quality & Regulatory Affairs & Clinical Director.
Consultant: Magalie HENNEQUIN, Quality & Regulatory Affairs & Clinical Director
Date Prepared: May 27th, 2024.

Name of Device:

Erisma® Lp Spinal Fixation System
Erisma® LP MIS

Common or Usual Name:

Thoracolumbosacral pedicle screw system

Classification Name:

Class II, 21 CFR 888.3070 – NKB

Predicate Devices

Erisma® Deformity Spinal System; Erisma® Lp Spinal Fixation System (K240872) **Primary predicate.**
Erisma® LP MIS (K162367) **Additional predicate**

Device Description

The modified Erisma® Lp Spinal Fixation System device is designed for use in the surgical treatment of spinal pathologies as outlined in the device's indications for use, which remains the same from the cleared Erisma® Deformity Spinal System; Erisma® Lp Spinal Fixation System device (K240872). The treatment consists of the fusion of two or several vertebrae in order to restore spinal stability, with or without any other endocanalar concomitant surgical procedure.

The cleared Erisma® Deformity Spinal System; Erisma® Lp Spinal Fixation System is composed of cannulated and non-cannulated monoaxial and polyaxial screws, crosslinks, rods, Offset Connectors, screw sets and associated instruments. Further, the implants used in the cleared Erisma® Lp Spinal

Fixation System device and modified Erisma® Lp Spinal Fixation System are both made of Ti6Al4V alloy per ASTM F136.

The modified Erisma® LP MIS is designed for use in the surgical treatment of spinal pathologies as outlined in the device's indications for use, which remains the same from the cleared Erisma® LP MIS device (K162367). The Erisma® LP MIS device is indicated for the surgical treatment of spinal pathologies by percutaneous access. The treatment consists of the stabilization of two or several vertebrae in order to restore spinal stability, with or without any other endocanalar concomitant surgical procedure.

The Erisma® LP MIS consists of cannulated extended pedicle screws and straight or pre-bent rods that can be used via posterior percutaneous surgical approach to provide the immobilization and the stabilization of spinal segments in mature patients as an adjunct to fusion in the treatment of instabilities or deformities of the thoracic, lumbar and sacral spine. The components are available in a variety of diameters and lengths to accommodate patient anatomy and are made from ISO 5832-3 or ASTM F136 medical grade Titanium alloy.

The subject of this submission is the extend to the Erisma® Lp Spinal Fixation System and the Erisma® LP MIS, with the addition of new components: 'Uniplanar Screws'

Intended Use / Indications for Use

When used as a pedicle screw fixation system of the non- cervical posterior spine in skeletally mature patients using allograft and/or autograft, the Erisma® LP Spinal System is indicated as an adjunct to fusion for the following indications: Degenerative Disc Disease (Define as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); degenerative spondylolisthesis with objective evidence of neurologic impairment; severe spondylolisthesis (grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; fracture; dislocation; scoliosis; kyphosis; spinal tumor; failed previous fusion (pseudarthrosis)

The Erisma® LP MIS components are intended for percutaneous, posterior, non-cervical pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative disc disease (Define as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Degenerative spondylolisthesis with objective evidence of neurologic impairment,
- Severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint,
- Fracture,
- Dislocation,
- Scoliosis,
- Kyphosis,
- Spinal tumor,
- Failed previous fusion (pseudarthrosis).

Summary of Technological Characteristics

The modified Erisma® Lp Spinal Fixation System and the modified Erisma® LP MIS devices possess the same technological characteristics as the predicate devices. No changes have been made as part of this submission. The fundamental scientific technology of the subject devices remains unchanged.

Performance Data

Dynamic compression bending test and Static torsion mechanical verification test according to ASTM F1717 and static torsional grip test according to ASTM F1798 were performed to characterize the subject modification addressed in this notification.

Conclusions

The modified Erisma® Lp Spinal Fixation System is substantially equivalent to the cleared Erisma® Deformity Spinal System; Erisma® Lp Spinal Fixation System device (K240872) and the cleared Erisma® LP MIS (K162367).
The modified Erisma® Lp Spinal Fixation System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Performance data demonstrate that the subject devices are substantially equivalent to the already cleared Erisma® Deformity Spinal System; Erisma® Lp Spinal Fixation System device (K240872) and the cleared Erisma® LP MIS (K162367). Thus, the modified Erisma® Lp Spinal Fixation System is substantially equivalent to the predicate devices.