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

April 26, 2024

Re: K240872
Trade/Device Name: Erisma® Deformity Spinal System; Erisma® Lp Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: March 18, 2024
Received: March 29, 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: 2024.04.26 09:58:28 -04'00'

for

Colin O'Neill, MBE
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)*

K240872

Device Name

Erisma® Deformity Spinal System ;
Erisma® Lp Spinal Fixation System

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® Deformity 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; deformities (Scoliosis, kyphosis); spinal tumor; failed previous fusion (pseudarthrosis).

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 (discogenic pain 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.

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510(K) SUMMARY

Erisma® Deformity Spinal System
Erisma® LP Spinal Fixation System

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

CLARIANCE
18, rue Robespierre
62217 Beaurains, France

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Contact Person: Magalie HENNEQUIN, Quality & Regulatory Affairs & Clinical Director.
Consultant: Magalie HENNEQUIN, Quality & Regulatory Affairs & Clinical Director
Clariance Inc. 42547 Farrington Street Dallas, Texas 75207

Date Prepared: March 19th, 2024

Name of Device:

Erisma® Deformity Spinal System
Erisma® LP Spinal Fixation System

Common or Usual Name:

Thoracolumbosacral pedicle screw system

Classification Name:

Class II, 21 CFR 888.3070 - NKB

Predicate Devices

Erisma® LP Spinal Fixation System manufactured by CLARIANCE SAS (K170163) primary predicate.
XIA® 4.5 Spinal System, XIA® 4.5 Cortical Trajectory, XIA® 3 Spinal System, Serrato® Spinal System, XIA® Growth Rod Conversion Set, XIA® II Spinal System, XIA® Precision System, XIA® Anterior, Diapason® Spinal System, Opus™ Spinal System, Radius® Spinal System, Mantis® Spinal System, Mantis® Redux manufactured by Stryker Spine (K222684).

Device Description

The Erisma® Deformity Spinal 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® Lp Spinal Fixation System device (K170163). 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 Erisma® Deformity Spinal System device is an extension of the already cleared Erisma® Lp Spinal Fixation System.

The cleared Erisma® Lp Spinal Fixation System are composed of cannulated and non-cannulated monoaxial and polyaxial screws, crosslinks, rods, screw sets and associated instruments. Further, the implants used in both the cleared Erisma® Lp Spinal Fixation System device and Erisma® Deformity Spinal System are made of Ti6Al4V alloy per ASTM F136.

The subject of this submission is the extend to the Erisma® Lp Spinal Fixation System, with the addition new components 'Closed Offset Connectors' and commercialization of the 'Open Offset Connectors' provided in the Erisma® Deformity Spinal System range.

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® Deformity 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; deformities (Scoliosis, kyphosis); spinal tumor; failed previous fusion (pseudarthrosis).

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 (discogenic pain 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)

Technological Characteristics

The proposed modification to the 510(k) cleared Erisma® LP Spinal System (K170163) consist in the addition new components 'Closed Offset Connectors' and commercialization of the 'Open Offset Connectors' provided in the Erisma® Deformity Spinal System range. The proposed offset connectors are made from the same material as the as the primary predicate device. These offset connectors are available in several sizes. The proposed modification is present in the reference device and does not raise different types of safety or effectiveness questions.

Performance Data

Static axial load gripping tests and static axial torque gripping tests per ASTM F1798 was performed to characterize the subject modification addressed in this notification.

Conclusions

The modified Erisma® Lp Spinal Fixation System and Erisma® Deformity Spinal System devices are substantially equivalent to the Erisma® Lp Spinal Fixation System (K170163) and additional predicate. The modified Erisma® Lp Spinal Fixation System and Erisma® Deformity Spinal System have the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Performance data demonstrate that the subject devices have a substantially equivalent safety and effectiveness profile compared to the Erisma® Lp Spinal Fixation System (K170163). Thus, the modified Erisma® Lp Spinal Fixation System and Erisma® Deformity Spinal System are substantially equivalent.