DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 14, 2017

CLARIANCE SAS
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K170163
Trade/Device Name: 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: January 18, 2017
Received: January 18, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K170163

Device Name
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® LP Spinal Fixation 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® LP Spinal Fixation System

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

CLARIANCE SAS
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Phone: +33(0)3 2116 1215
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Contact Person: Pascal ROKEGEM, Chief Technology Officer
Consultant: Janice Hogan, Regulatory Counsel at Hogan Lovells US LLP
Date Prepared: February 10, 2017

Name of Device and Name

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 manufactured by CLARIANCE SAS (K153326, K120469): primary predicate
Expedium® manufactured by DePuy Spine (K130877): additional predicate (CoCr rods)

Purpose of the Special 510(k) notice.

The modified Erisma® LP is a modification to the 510(k) approved Erisma® LP predicate (K153326). The modification consists in the addition of straight and pre-bent rods made from medical grade cobalt-chromium alloy per ASTM F1537. These rods have similar dimensions and design as those already cleared under K153326 for the Erisma® LP predicate device.

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 (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)

Device Description

The Erisma® LP instrumentation is designed for the surgical treatment of spinal pathologies. The treatment consists in the fusion of two or several vertebrae in order to restore spinal stability, with or without any other endocanalar concomitant surgical procedure.

The Erisma® LP spinal system is composed of rods (straight or pre-bent) fixed on the spine with pedicle screws. The Erisma® LP includes monoaxial and polyaxial pedicle screws (cannulated or not), monoaxial and polyaxial pedicle screws with breaking tabs, as well as transverse link which connects two rods altogether.

The implants used in the Erisma® LP system are available in a variety of diameters and lengths to accommodate patient anatomy and are made of medical grade titanium alloy per ASTM F136 or cobalt-chromium alloy per ASTM F1537.

The Erisma® LP procedures are performed using a set of surgical instruments common for posterior spinal fixation approach. Most of the instruments provided are common surgical tools used in these types of posterior fixation of the spine.

Technological Characteristics

The proposed modification to the 510(k) cleared Erisma® LP device (K153326) consist in the addition of rods (straight and pre-bent) made of medical grade cobalt-chromium alloy per ASTM F1537. The proposed rods are made from the same material as the additional predicate device. These rods vary in size and geometries and are equivalent to those cleared for the company's Erisma® LP predicate device (K153326). The proposed modification is present in the reference device and does not raise different types of safety or effectiveness questions.

Performance Data

Dynamic Axial Compression testing per ASTM F1717 was performed to characterize the subject modification addressed in this notification.

Substantial Equivalence

The modified Erisma® LP has the same intended use and similar indications, principles of operation, and technological characteristics as 510(k) approved Erisma® LP (K153326). The minor difference in the technological characteristics of the modified Erisma® LP does not raise any new questions of safety or effectiveness. Performance data demonstrates that the modified Erisma® LP is as safe and effective as company's Erisma® LP predicate device (K153326). Thus, the modified Erisma® LP is substantially equivalent to its predicate devices.

Conclusions

The Erisma® LP Spinal Fixation System is substantially equivalent to the predicate devices.