DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

CLARIANCE, SAS
% Ms. Janice M. Hogan
Partner
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

March 8, 2016

Re: K153326
Trade/Device Name: Erisma®-LP Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: February 12, 2016
Received: February 12, 2016

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 Parts 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 yours,

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)*

K153326

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 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)

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510(k) SUMMARY

CLARIANCE's Modified Erisma® - LP Spinal Fixation System

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

CLARIANCE, SAS
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62217 Beaurains, France

Phone: +33(0)3 2116 1215
Facsimile: +33(0)3 2115 5073

Contact Person: Pascal ROKEGEM, Chief Technology Officer

Date Prepared: November 18, 2015

Name of Device and Name/Address of Sponsor

CLARIANCE – Erisma®-LP Spinal Fixation System
18 rue Robespierre
62217 Beaurains, France

Common or Usual Name

Non cervical pedicle spine System

Classification Name

Class III, 21 CFR 888.3070, NKB
Class II, 21 CFR 888.3070, MNH and MNI

Predicate and Reference Devices

Erisma LP manufactured by CLARIANCE SAS (K120469) (Primary Predicate)
Xia Spine System manufactured by Howmedica Osteonics Corp (now Stryker) (K001272) (Reference Device)
Xia 3 Spine System manufactured by Stryker Spine (K142381) (Reference Device)
CD Horizon LEGACY manufactured by Medtronic (K143569) (Reference Device)

Purpose of the Special 510(k) notice.

The Erisma®-LP is a modification to the cleared Erisma®-LP to add screws with breaking tabs, improve screw/head fixation, and change from single to double thread, as well as add additional screw dimensions and instrument modifications.

Indications

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 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®-LP system is composed of rods fixed on the spine with pedicle screws. The Erisma®-LP includes monoaxial and polyaxial screws cannulated or not and monoaxial and polyaxial screws with or without breaking tabs, as well as a transverse link which connects two rods altogether.

The implants used in the Erisma®-LP system are made of ISO 5832-3 or ASTM F136 medical grade titanium alloy.

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. Those instruments are considered Class I, general purpose, manual orthopedic instruments encompassed within the regulation in 21CFR 888.4540.

Technological Characteristics comparison

The modified device is made from the same materials as the company's cleared predicate device. The slight differences between the predicate and modified device include the addition of breaking tabs, improved polyaxial screw assembly fixation strength, and change in screw threading. None of these changes raise different types of safety or effectiveness questions and are present in reference devices.

Performance Data

Bench testing was performed to establish equivalence included:

- Dynamic ASTM F1717-15 testing;
- Pull-Out ASTM F543 testing.

Substantial Equivalence

The Erisma®-LP has the same intended use and indications for use, as well as very similar principles of operation and technological characteristics as the cleared Erisma® LP. The minor differences in the technological characteristics do not raise different questions of safety or effectiveness. Performance data demonstrates that the Erisma® LP is substantially equivalent to its predicate devices.

Conclusion

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