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

October 27, 2016

Re: K162367
Trade/Device Name: Erisma® LP MIS
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: August 23, 2016
Received: August 23, 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K162367

Device Name: Erisma® LP MIS

Indications for Use

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

☒ 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 MIS

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

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Contact Person: Pascal Rokegem, Chief Technology Officer

Date Prepared: October 25, 2016

Name of Device and Name/Address of Sponsor

Erisma® LP MIS

Common or Usual Name

Non cervical Minimal Invasive Pedicle Spinal System

Classification Name

Pedicle Screw Spinal System

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

Predicate Devices

Erisma LP Spinal Fixation System Manufactured by CLARIANCE SAS (K153326) (Primary predicate device)

ES2 Spinal System Manufactured by STRYKER Spine (K122845) (Additional predicate device)

Indications for Use

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).

Technological Characteristics

The Erisma® LP MIS device is intended to be used 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 Erisma® LP MIS also contains surgical instruments common for posterior percutaneous spinal fixation approach. The primary purpose of this submission is to extend the breakoff tabs of the pedicle screws to allow for minimally invasive surgery. The documentation provided demonstrates that the Erisma® LP MIS is substantially equivalent to the predicate devices in terms of material, design and indications for use.

Performance Data

Bench Testing was performed to establish equivalence including:

- Dynamic ASTM F1717 testing
- Sterilization validation

Substantial Equivalence

The Erisma® LP MIS device has the same intended use and indications, as well as very similar principles of operation and technological characteristics to the cleared company's Erisma® LP (K153326) and the Stryker Spine ES2 Spinal System (K122845) predicate

devices. The primary change to the system is the extension of the breakable tabs to allow for MIS insertion, which is technologically similar to the Stryker Spine ES2 Spinal System. These changes do not raise different safety or effectiveness questions. Performance data demonstrates that the Erisma® LP MIS is substantially equivalent to its predicate devices.

Conclusions

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