February 26, 2021

Clariance, SAS
% Jennifer Daudelin
Senior Project Manager
M Squared Associates, INC
127 West 30th Street, Floor 9
New York, New York 10001

Re: K202956
Trade/Device Name: Erisma LP Navigated Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 22, 2021
Received: January 25, 2021

Dear Jennifer Daudelin:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For: Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202956

Device Name

Erisma®-LP Navigated Instruments

Indications for Use *(Describe)*

Erisma®-LP Navigated Instruments are intended to be used in the preparation and placement of Erisma® Screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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

The following information is provided as required by 21 CFR § 807.87 for the Clariance SAS 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the Clariance SAS is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device(s).

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Date Prepared: September 25, 2020

Proposed Class: II

Proprietary Name: ERISMA® LP_NAVIGATED INSTRUMENTS

Common Name: Stereotaxic Instrument

Classification Name: Stereotaxic Instrument

Regulation Number: 21 CFR 882.4560

Product Codes: OLO

Predicate Device(s):

Manufacturer	Device Name	510(k) Number	Procode	Class
Primary Predicate:				
Medtronic Sofamor Danek USA	Navigated CD Horizon Solera Screwdriver/Taps	K140454	OLO, HBE	II
Reference Devices:				
Clariance SAS	Erisma-Lp Spinal Fixation System	K153326	NKB	II
Clariance SAS	Erisma®-Lp Mis	K162367	NKB	II

Indications for Use

Erisma®-LP Navigated Instruments are intended to be used in the preparation and placement of Erisma® LP screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation™ System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Device Description

The Erisma®-LP Navigated Instruments are manual, non-sterile, reusable surgical instruments for use with the Medtronic StealthStation™ Navigation System to assist the surgeon in locating anatomical structures in either open, minimally invasive or percutaneous procedures for preparation and placement of the Clariance Erisma®-LP, Erisma®- MIS pedicle screw implants. The Erisma®-LP Navigated Instruments include the following instruments: Drivers, Tap, Bone Awl, Probes. The instrumentation is designed for use with the Medtronic StealthStation™ Navigation System hardware and software. These instruments are made of medical quality stainless steel according to the ASTM F899 and titanium alloy according to the ASTM F136.

Performance Data – Non-Clinical

A series of mechanical tests have been performed to support the substantial equivalence of the Erisma®-LP Navigated Instruments with the Medtronic Navigated Instruments cleared in 510(k), K140454. CLARIANCE performed tests to demonstrate the compatibility between Erisma®-LP Navigated Instruments and Medtronic Naclock Tracker, the ability of Erisma®-LP Navigated Instruments to be registered by Medtronic StealthStation™ System, and a simulation of pedicle insertion, all of which demonstrated the substantial equivalence of the system to legally marketed devices.

There have been no changes to the manufacturing methods or patient contacting materials from the predicate Erisma® instruments cleared in 510(k)s K153326 and K162367; therefore, no new testing was required to demonstrate biocompatibility of the Erisma®-LP Navigated Instruments.

Substantial Equivalence

The Erisma®-LP Navigated Instruments has the same indications for use and similar design features as compared with the predicate systems. The bench testing demonstrates that the performance characteristics of the Erisma®-LP Navigated Instruments are equivalent to those of the other legally marketed stereotaxic instrument devices, and therefore supports a determination of Substantial Equivalence for the proposed indications for use. Any differences between the subject and predicate devices would not render the device NSE, affect the safety or effectiveness, or raise different questions of safety and effectiveness.