June 06, 2019

Spineart SA
℅ Meredith May
Vice President
Empirical Consulting LLC
4628 Northpark Dr
Colorado Springs, Colorado 80918

Re: K183630
Trade/Device Name: SPINEART Navigation Instrument System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 3, 2019
Received: May 6, 2019

Dear Meredith May:

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
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 on last page.

510(k) Number *(if known)*
K183630

Device Name
SPINEART® Navigation Instrument System

Indications for Use *(Describe)*

The SPINEART® Navigation Instrument System reusable instruments are intended to be used during the preparation and placement of Spineart screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The SPINEART® Navigation Instrument System reusable instruments are specifically 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 a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for 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.

5. 510(K) SUMMARY

Submitter's Name:	Spineart SA
Submitter's Address:	Chemin du Pré- Fleuri 3 1228 Plan-les-Ouates Switzerland
Submitter's Telephone:	+41 22 570 1200
Contact Person:	Meredith Lee May MS, RAC Empirical Consulting 719.337.7579 MMay@EmpiricalConsulting.com
Date Summary was Prepared:	21-Dec-18
Trade or Proprietary Name:	SPINEART® Navigation Instrument System
Common or Usual Name:	Orthopedic Stereotaxic Instrument
Classification:	Class II per 21 CFR §882.4260
Product Code:	OLO
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SPINEART® Navigation Instrument System reusable instruments are surgical instruments for use with the Medtronic® StealthStation® Navigation System to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants.

The SPINEART® Navigation Instrument System includes the following: Screwdrivers, Taps, Drills, and Drill Guides.

The SPINEART® Navigation Instrument System are to be used with the following Spineart Systems:

- Romeo® 2
- Romeo® 2 MIS
- Perla® Cervico-thoracic Fixation System

All instruments are made of stainless steel per ASTM F899. Taps range in size from Ø4mm to Ø7.5mm for the Romeo® 2 systems and from Ø3mm to Ø4mm for the Perla system.

The SPINEART® Navigation Instrument System instruments are not compatible with implants from other manufacturers.

The SPINEART® Navigation Instrument System are designed for use only with Medtronic StealthStation Navigation System hardware and software.

INDICATIONS FOR USE

The SPINEART® Navigation Instrument System reusable instruments are intended to be used during the preparation and placement of Spineart screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The SPINEART® Navigation Instrument System reusable instruments are specifically 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 a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for use
- Materials of manufacture
- Principle of operation
- Device technology
- Sizes
- Mechanical performance
- Packaging (materials and processes)

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K143628/K140454/ K143375	Medtronic Navigated Instruments	Medtronic Sofamor Danek USA, Inc.	Primary
K172517	SeaSpine Navigation System	SeaSpine Orthopedics Corporation	Additional
K153203	Navigation Instruments	Globus Medical, Inc.	Additional
K140948	ROMEO® Posterior Osteosynthesis System	Spineart	Reference
K153386	PERLA® Posterior Cervico-Thoracic Fixation System	Spineart	Reference

PERFORMANCE DATA

Design validation testing including connection, registration, simulated use, and accuracy was conducted to ensure that the SPINEART® Navigation Instrument System instruments are acceptable for their intended use, to ensure functionality and compatibility with the Medtronic StealthStation®, and to demonstrate substantial equivalence to the predicate instruments.

Connection testing evaluated the connection between the NavLock Tracker and the instruments. Registration testing was performed to ensure that the instruments can be registered to the StealthStation®. Simulated use testing was completed to verify successful implantation of Spineart screws by the SPINEART® Navigation Instrument System. Accuracy testing per ASTM F2554-10, "Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems," was completed for comparison to the predicate instruments. The results of this non-clinical testing show that the performance of the SPINEART® Navigation Instrument System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the SPINEART® Navigation Instrument System is substantially equivalent to the predicate device.