MiRus, LLC
Jordan Bauman
Director of Regulatory Affairs and Quality
2150 Newmarket Parkway Suite 108
Marietta, Georgia 30067

June 17, 2019

Re: K182524
Trade/Device Name: GALILEO Spine Alignment Monitoring System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 13, 2019
Received: May 16, 2019

Dear Jordan Bauman:

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

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: 06/30/2020

See PRA Statement below.

510(k) Number *(if known)*

K182524

Device Name

GALILEO™ Spine Alignment Monitoring System

Indications for Use *(Describe)*

The GALILEO™ Spine Alignment Monitoring System is intended to provide intra-operative measurements to a surgeon to aid in the selection and positioning of orthopedic implant system components, relative to anatomical structures and reference axes.

The GALILEO™ Spine Alignment Monitoring System is indicated for patients undergoing orthopedic spine surgery where the use of stereotactic surgery is considered safe and effective, and where a reference to a rigid spinal anatomical structure, such as a vertebral body, can be identified relative to the anatomy. The system aids the surgeon in controlling spinal alignment.

Example spine surgical procedures include:

- Spinal deformity correction
- Spinal fusion

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

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

I. SUBMITTER

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Tel: (844) 367-0078
Fax: (844) 367-2348

II. OFFICIAL CORRESPONDENT

Jordan Bauman
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Tel: (844) 367-0078
Fax: (844) 367-2348

III. DATE PREPARED

May 13, 2019

IV. DEVICE

Name of Device	GALILEO™ Spine Alignment Monitoring System
Common Name	Orthopedic Stereotaxic Instrument
Classification Name	21 CFR §882.4560
Regulatory Class	Class II
Product Codes	OLO
Submission Type	Traditional 510(k)

V. PREDICATE DEVICE

Primary:
Intellijoint HIP™ System (K133759)
Reference:
Zimmer iASSIST® Knee System (K122326)

VI. DEVICE DESCRIPTION

The GALILEO™ Spine Alignment Monitoring System provides intra-operative real-time measurement of sagittal plane spine alignment parameters such as Lordosis and Kyphosis. The system consists of Orientation Sensing Modules (OSM) that are attached to vertebrae of interest with the patient in prone position. The OSM's are battery-powered devices containing inertial sensors that measure vertebral alignment changes and communicate the information wirelessly to a computer. The computer software calculates sagittal plane spinal alignment parameters in real-time based on the OSM measurements and displays the information on a touch screen tablet.

VII. INTENDED USE/ INDICATIONS FOR USE:

The GALILEO™ Spine Alignment Monitoring System is intended to provide intra-operative measurements to a surgeon to aid in the selection and positioning of orthopedic implant system components, relative to anatomical structures and reference axes.

The GALILEO™ Spine Alignment Monitoring System is indicated for patients undergoing orthopedic spine surgery where the use of stereotactic surgery is considered safe and effective, and where a reference to a rigid spinal anatomical structure, such as a vertebral body, can be identified relative to the anatomy. The system aids the surgeon in controlling spinal alignment.

Example spine surgical procedures include:
- Spinal deformity correction
- Spinal fusion

VIII. TECHNOLOGICAL COMPARISONS TO THE PREDICATE

Both the predicate and subject devices provide intra-operative measurements to a surgeon to aid in the selection and positioning of orthopedic implant system components. Differences in tracking technology between the subject and predicate do not raise any new questions of safety and effectiveness. The reference device - iASSIST® Knee System (K122326) - is a legally marketed device that utilizes similar battery-powered inertial sensing technology as the subject device to track the orientation of instruments and anatomy.

IX. PERFORMANCE DATA

The following performance data supports the safety and efficacy and substantial equivalence of the GALILEO™ Spine Alignment Monitoring System.

1. Performance tests were performed under simulated bench test conditions to verify the implementation of the software algorithms and overall system accuracy covering all functional steps including: calibration, sagittal plane registration, vertebral registration, and sagittal plane spine alignment measurements.
2. Simulated use testing involving sawbones and cadaver specimen were performed to verify and validate the overall system performance and use and to compare system measurements with clinically accepted standardized radiographic measurements. The results demonstrated that the GALILEO™ Spine Alignment Monitoring System satisfied all user needs and intended use requirements.
3. Electrical, electromagnetic compatibility, and wireless telecommunication tests were performed to demonstrate compliance to IEC 60601-1, IEC 60601-1-2, and FCC 47 CFR part 15.
4. Software tests were performed to ensure that the required functionalities and features were implemented without the introduction of hazardous anomalies.
5. Biocompatibility was achieved by using materials with established biocompatibility for characteristics for all patient contacting instruments and components.
6. Sterilization and packaging validation tests were performed for single-use components in compliance with ISO 14937 and ISO 11607 to ensure a SAL of 10^{-6} over the shelf life of the product.

X. CONCLUSION

Based on the intended use, performance testing, and comparison to the predicate device, the GALILEO™ Spine Alignment Monitoring System has been shown to be substantially equivalent to the legally marketed predicate device and does present any new questions of safety and effectiveness.