March 13, 2023

Fusion Robotics, LLC
℅ Sarah Braun
Senior Regulatory Affairs Specialist
Integrity Implants Inc. dba Accelus
354 Hiatt Drive
Palm Beach Gardens, Florida 33418

Re: K223350
Trade/Device Name: Remi Robotic Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 22, 2022
Received: November 23, 2022

Dear Sarah Braun:

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,

Jesse Muir -S

For: Shumaya Ali, M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223350

Device Name
Remi Robotic Navigation System

Indications for Use *(Describe)*
The Remi Robotic Navigation System is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on a 3D imaging scan or 2D fluoroscopic images. The Remi Robotic Navigation System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (L1-S1). The system is designed for lumbar pedicle screw placement with the patient in the prone position and is compatible with the Accelus LineSider Spinal System.

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.

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510(k) Owner	Fusion Robotics, LLC 168 Centennial Parkway, Unit 170 Louisville, CO 80027 USA
Contact Person	Sarah Braun Senior Regulatory Affairs Specialist Tel: 423-838-4454 Email: sbraun@accelusinc.com
Date Prepared	11/22/2022
Classification Reference	21 CFR 882.4560
Product Code	OLO
Common/Usual Name	Stereotaxic Instrument
Trade/Proprietary Name	Remi Robotic Navigation System
Predicate Device(s)	Remi Robotic Navigation System (K223070) EXCELSIUS GPS (K171651)

The Remi Robotic Navigation System (Remi) is an image guided system primarily comprised of a computer workstation, software, a trajectory system, including a targeting platform, a camera, and various image guided instruments intended for assisting the surgeon in placing screws in the pedicles of the lumbar spine. The system operates in a similar manner to other optical-based image guided surgery systems:

1. The patient is placed in the appropriate position on the OR table.
2. The compact tracking Camera is rigidly affixed to the OR table using a multi-functional mechanical support arm in the appropriate position to track the surgical site.
3. The Camera is also affixed to a pin placed in the patient's iliac to provide a fixed location relative to the patient's spinal anatomy.
4. The Targeting Platform is affixed to the OR Table using a multi-functional mechanical support arm, ensuring that the Targeting Platform has sufficient range of motion to be placed over the surgical site.

5. If a 3D imaging system is being used, the Registration Array is affixed to the Targeting Platform and positioned over the planned surgical site.
6. If 2D fluoroscopic system is being used, the C-Arm Grid Plate, 9900 9" is installed onto the fluoroscopic imaging system.
7. The appropriate area of spine (L1-S1) is Imaged with a validated imaging system.
8. The images are transferred to the Remi system workstation, which reconstructs the images and uses the registration array image (for 3D images) or the C-Arm Grid Plate Tracker image (for 2D fluoroscopic Images) to register the patient's spine relative to the Camera location.
9. The registration is confirmed by placing an image guided instrument with an Instrument Tracker at various points in the surgical field.
10. The surgical paths are then planned. If the procedure is using 3D images, this is done on the workstation. If the procedure is using 2D fluoroscopic images, the Planning Probe and workstation are utilized to capture the desired position for target pedicle screw placement.
11. The Targeting Platform is gross positioned manually close to the first surgical plan location.
12. The Targeting Platform is activated to set the fine location and the trajectory based on the surgical plan.
13. Instruments with tracking arrays can now be used through the tool guide of the Targeting Platform to prepare the pedicle and place a pedicle screw.

Intended Use/Indications for Use

The Remi Robotic Navigation System is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on a 3D imaging scan or 2D fluoroscopic images. The Remi Robotic Navigation System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (L1-S1). The system is designed for lumbar pedicle screw placement with the patient in the prone position and is compatible with the Accelus LineSider Spinal System.

Substantial Equivalence

The proposed Remi Robotic Navigation System (Remi) allows the use of a 2D fluoroscopic Imaging system. The system validated for this submission is the GE OEC 9900 Elite 9" Image Intensifier (K122234). The indications for use has been updated to add 2D fluoroscopic images for use with the Remi system. Four instruments were added: Long Reference Arm (PN1075), Planning Probe (PN1115), C-

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Arm Grid Plate, 9900 9" (PN1138), C-Arm Grid Plate Tracker (PN1139). The software was updated to support the use of 2D fluoroscopic images. Changes include compatibility with the new instruments and an algorithm which corrects the distortion of the 2D fluoroscopic image.

Performance Testing – Bench

The following tests were performed to support the substantial equivalence of the subject Remi Robotic Navigation System (Remi) to its predicates:

- Navigation Accuracy Verification
- System Accuracy Validation
- Software System Test
- ASTM F2554 Accuracy Test
- Software Unit and Integration Tests

Testing was done to demonstrate that the updated requirement for this change was met and to ensure the risk profile of Remi was maintained. The testing shows that the use of the 2D fluoroscopic images with the Remi system is equivalent to the use of the validated 3D imaging systems.

Substantial equivalence analysis for Remi

Devices	Subject Device Remi Robotic Navigation System	Primary Predicate Device Remi Robotic Navigation System [K223070]	Secondary Predicate Device EXCELSIUS GPS [K171651]
Indications for Use	The Remi Robotic Navigation System is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on a 3D imaging scan or 2D fluoroscopic images. The Remi Robotic Navigation System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (L1-S1). The system is designed for lumbar pedicle screw placement with the patient in	The Remi Robotic Navigation System is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of a tool holder or Guide Tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous spinal procedures in reference to rigid patient anatomy and fiducials that can be identified on a 3D Imaging scan. The Remi Robotic Navigation System is indicated for assisting the surgeon in placing pedicle screws in vertebrae in the posterior lumbar region (LI-S1). The system is designed for lumbar pedicle screw placement with the patient in the prone position	The EXCELSIUS GPS™ is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

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	the prone position and is compatible with the Accelus LineSider Spinal System.	and is compatible with the Accelus LineSider Spinal System.	
Product Code	OLO	OLO	OLO
Principles of Operation	Same as Predicates.	• Intraoperative/preoperative images • Patient registration • Surgical planning • Real-time tracking of navigated instruments • Guidance of instruments	• Intraoperative/preoperative images • Patient registration • Surgical planning • Real-time tracking of • navigated instruments • Guidance of instruments
Input Images	3D Intraoperative images • Medtronic O-arm • GE OEC 3D • Ziehm-Vision RFD 3D • Stryker Airo TruCT 2D Fluoroscopic Images • GE OEC 9900 Elite 9" Image Intensifier (K122234)	3D Intraoperative images • Medtronic O-arm • GE OEC 3D • Ziehm-Vision RFD 3D • Stryker Airo TruCT	3D pre-operative images 3D intra-operative images 2D intra-operative images
Trajectory planning parameters	Same as Primary Predicate.	Entry point, target point, length of the instrument, diameter	Unknown
Localization method	Same as Primary Predicate	Optical System (infrared Camera)	Unknown
Camera system	Same as Primary Predicate	Monocular	Unknown
Controller	Same as Primary Predicate	Manual macro adjustments Force-controlled movement of Targeting platform	Unknown
Patient Registration Method	Same as Primary Predicate	Registration fixture in place during 3D intraoperative images	Intra-op CT: Registration fixture Pre-op CT: Fluoroscopic to pre-op CT merge Fluoroscopy: Registration fixture

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Accuracy verification on anatomical landmarks	Same as Predicates.	Yes	Yes
Real time display of instrument position	Same as Predicates.	Yes	Yes
Instrument Guidance	Same as Primary Predicate.	Trajectory and location set by Targeting platform. Instruments are manually positioned by the surgeon through the guide tube on the Targeting Platform.	Yes, instruments are used through the guide tube on the robotic arm or are manually positioned by the surgeon.
Patient fixation	Same as Primary Predicate.	Tracking Camera is fixed to OR table and the patient's iliac crest.	Reference is fixed to patient's bony structure such as a long bone, iliac crest, spinous process, vertebra, etc. for tracking system
Positioning accuracy (bench	Same as Primary Predicate.	0.74 ± 0.36mm (worst case) 95% CI: 1.46mm (worst case)	Unknown
Robot collision avoidance/detection	Same as Primary Predicate.	Manual movement of Trajectory Platform to gross location. Small fine tuning of Trajectory Platform location is automatic but is currently limited to cease when platform encounters a force greater than 9lbs.	Unknown

Conclusions

The subject device, Remi Robotic Navigation System, described in this submission shares a majority of the same technological characteristics as the primary predicate device, Remi Robotic Navigation System (K223070). The primary difference between the subject device and the primary predicate is the addition of validated 2D fluoroscopic imaging systems and the subsequent modification of the wording of the indications for use. Like the subject device, the secondary predicate, EXCELSIUS GPS (K171651) has the capability to rely on 2D intra-operative exam as the Input Images for the stereotaxic navigation of pedicle screw placement.

The verification and validation testing demonstrated that the characteristics of the subject Remi device are substantially equivalent to the predicate device. The subject device continues

to meet design requirements, is as safe and effective as the predicate device, and performs according to its intended use. The information presented in this 510(k) premarket notification demonstrates that the subject device is substantially equivalent to the predicate devices.