November 20, 2023

Fiagon GmbH
Dirk Mucha
Chief Technology Officer
Neuendorfstr. 23b
Hennigsdorf, Brandenburg 16761
Germany

Re: K230700
Trade/Device Name: RIWOtrack Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 20, 2023
Received: November 20, 2023

Dear Dirk Mucha:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

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)*
K230700

Device Name
RIWOtrack Navigation System

Indications for Use *(Describe)*
The RIWOtrack Navigation System is intended to continuously display the position and orientation of RIWOspine surgical instruments relative to the anatomy in medical image data in either open or minimal invasive orthopedic procedures.
The use 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 the spine or pelvis, can be identified relative to images of the anatomy.

This can include spinal procedures, where the target point for the procedure itself or for the access to the area of interest, is a rigid landmark, such as:
• Transforaminal procedure
• Interlaminar procedure

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) Summary
K230700

1. Submitter Information

Submitter: Fiagon GmbH
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Contact: Dirk Mucha
Chief Technology Officer

2. Device Information

Trade Name: RIWOtrack Navigation System

Common Name: Image guided surgery system

Classification: Class II per 21 CFR 882.4560

Classification Name: Orthopedic Stereotaxic Instrument

Product Code: OLO

3. Predicate Device Information

Predicate device: joimax® Intracs® em System (K192663)

4. Device Description

The RIWOtrack Navigation System is an image guided surgery system, visualizing instrument positions on intraoperative fluoroscopy images (AP and LAT) utilizing electromagnetic tracking technology. The positions of the instrument and of the patient localizer, both equipped with sensors, are localized within an electromagnetic field, generated

by a field generator, called navigation sensor. The principle of navigation is based on electromagnetic spatial measuring of localizer element in a generated electromagnetic field. The display of navigation information requires an image-to-patient registration procedure. During registration procedure, the Navigation System determines the coordinate transformation between the physical position of the patient and the position of the patient in intraoperative scans by means of autodetection of x-ray marker of a device called MapperBridge. Thereafter, the spatial position of the instrument is displayed superimposed to the image data. The navigation information is updated with a rate of 15 to 45 Hz.

5. Intended Use

The RIWOtrack Navigation System is intended to continuously display the position and orientation of RIWOspine surgical instruments relative to the anatomy in medical image data in either open or minimal invasive orthopedic procedures.

Indications for Use RIWOtrack Navigation System and Predicate Devices

Device	Indications for Use
RIWOtrack Navigation System	The RIWOtrack Navigation System is intended to continuously display the position and orientation of RIWOspine surgical instruments relative to the anatomy in medical image data in either open or minimal invasive orthopedic procedures. The use 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 the spine or pelvis, can be identified relative to images of the anatomy. This can include spinal procedures, where the target point for the procedure itself or for the access to the area of interest, is a rigid landmark, such as: • Transforaminal procedure • Interlaminar procedure
Joimax Intracs System (K192663)	The joimax ® Intracs ® em Navigation System is intended to continuously display the position and orientation of joimax ® surgical instruments relative to the anatomy in medical image data in either open or minimal invasive orthopedic procedures. The use 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 the spine or pelvis, can be identified relative to images of the anatomy. This can include spinal procedures, where the target point for the procedure itself or for the access to the area of interest, is a rigid landmark, such as: • Transforaminal procedure • Interlaminar procedure

6. Comparison of Technological Characteristics

At a high level, the RIWOtrack Navigation System is based on the same technological elements as the joimax® Intracs® em System. Both systems deploy the same electromagnetic technology, have NDI technology installed in their components and are run by a navigation software. The systems are designed to facilitate spinal surgical procedures by localization of surgical instruments and patient anatomy.

The RIWOtrack System has the same technological characteristics as the predicate device including design, intended use, major system components, principle of operation and image-to-patient registration method. The similarities and differences are summarized in the table below:

Feature	RIWOtrack Navigation System	Joimax® Intracs® em [K192663]
Class	Class II 21 CFR 882.4560 Product code: OLO	Class II 21 CFR 882.4560 Product code: OLO
Indications for Use	(see above)	(see above)
Anatomic site	Spine	Spine
Tracking Method	Electromagnetic	Electromagnetic
Computer	Intel-based PC	Intel-based PC
Principle of Operation	Localization of sensors attached to instruments within a defined electromagnetic field	Localization of sensors attached to instruments within a defined electromagnetic field
Image modality	x-ray (fluoroscopy)	x-ray (fluoroscopy)
View	AP and Lateral View, Video Input	AP and Lateral View, Video Input
Field generator	NDI Navigation senor Aurora Mounted to articulating metal arm	NDI Navigation senor Aurora Mounted to articulating metal arm
EM instrumentation	RIWOtrack instruments are tracked by electromagnetic sensors which can be attached to RIWOspine surgical instruments	joimax® instruments are tracked by electromagnetic sensors which can be attached to the joimax® surgical instrument
Method of registration	Autodetection of x-ray markers of a reference device in intraoperative fluoroscopy images	Autodetection of x-ray markers of a reference device in intraoperative fluoroscopy images
System accuracy	Mean system level accuracy: Position error < 2mm Angular error < 2°	Mean system level accuracy: Position error ≤ 2mm Angular error ≤ 2°

7. Performance Data

The following tests were performed to substantiate the performance claims and to support substantial equivalence to the predicate device:

- Electrical safety according to IEC 60601-1
- Electromagnetic compliance according to IEC 60601-1-2
- Accuracy bench testing for each instrument probe and localizer.
- Software verification and validation
- Cleaning validation
- Sterilization validation
- Biocompatibility validation

The RIWOtrack Navigation System met all specified criteria. and did not raise new safety or performance concerns. Based on the performance testing, it was found that the RIWOtrack Navigation System has a similar safety and effectiveness profile to the predicate device.

8. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate device, the RIWOtrack Navigation System demonstrates to be substantially equivalent to the predicate device identified in this submission and it does not present any new issues of safety or effectiveness.