July 30, 2020

joimax GmbH
Gary Mocnik
Official Correspondent
Amalienbadstrasse 41, RaumFabrik 61
Karlsruhe, 76227 Germany

Re: K192663
Trade/Device Name: Joimax Intracs System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 26, 2020
Received: June 30, 2020

Dear Gary Mocnik:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192663

Device Name
joimax® Intracs® em System

Indications for Use *(Describe)*
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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

I. SUBMITTER

joimax® GmbH
Amalienbadstrasse 41
RaumFabrik 61
76227 Karlsruhe, Germany

Contact person: Gary Mocnik
Phone: (949) 433-0413
Date prepared: September 23, 2019

II. DEVICE
Name of the device: joimax® Intracs® em System
Common or usual name: Surgical navigation system
Classification name: Orthopedic Stereotaxic Instrument
Regulatory Class: 2
Regulation Number: 21 CFR 882.4560
Product Code: OLO

III. PREDICATE DEVICE
StealthStation S8 Spine Software (K170011)

IV. DEVICE DESCRIPTION
The joimax® Intracs® em System is a surgical navigation system based on electromagnetic (EM) tracking technology, designed specifically for applications in minimally invasive spine surgery. The system displays instrument position relative to the patient's anatomy.

V. INDICATIONS FOR USE
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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE
At a high level, the subject and predicate device are based on the following same technological elements:

- Both devices are design to facilitate spinal surgical procedures by

localization of surgical instruments and patient anatomy

- Both devices utilize electromagnetic (EM) technology to facilitate localization of the instruments and patient anatomy

The subject joimax® Intracs® em System has the same technological characteristics as the predicate device including design, intended use, major system components and function. The similarities and differences are summarized in the table below:

	joimax® Intracs® em System	**StealthStation S8 Spine Software (K170011).**
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 or localization of reflectors by cameras
Anatomical Site	Spine	Spine
Surgical type	Minimally invasive	Minimally invasive, open
Imaging modalities (Spine)	X-Ray (fluoroscopy)	X-Ray (fluoroscopy)
Control Mechanism (hardware)	Tracked instruments, touch screen or mouse	touch screen or mouse
Scanner interface Technology	Network Connectivity CD, DVD, USB DICOM Import	Network Connectivity CD, DVD, USB DICOM Import DICOM Export
View (display features)	AP and Lateral View, Video Input	Look Sideways 3D Anatomic Orthogonal Trajectory 1 and 2 Trajectory Guidance Look Ahead Probe's Eye AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input
Localization Technology	EM	Optical or EM
Instrument interface	EM	Optical or EM
EM Emitter Types	Side	Side, Flat
EM Instrumentation	joimax® instruments are tracked by electromagnetic sensors which can be attached to the instrument	Medtronic instruments tracked via electromagnetic localization technology located within the instrument and patient trackers
Software Interface (GUI)	Basic white and black-style with 4 main workflow steps. Controls are located on the right side of each view	Basic gray and black style with 4 main tasks and tab interface to access tools. Controls on the right.
Computer	Intel-based PC	Intel-based PC
Network Connectivity	Connection Type: Standard Ethernet	Connection Type: Standard Ethernet 2.4 gHz and 5.0 gHz Wireless connection
System Accuracy	System Level Accuracy with a mean positional error of ≤2.0 mm and a mean trajectory error of ≤2°.	System Level Accuracy with a mean positional error of 2.0 mm and a mean trajectory error of 2°.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence.

- Electrical safety (IEC 60601-1)
- Electromagnetic compatibility (IEC 60601-1-2)
- Usability
- Performance testing (accuracy)
- Functional testing
- Software verification
- Performance testing with phantoms and human cadavers
- Biocompatibility evaluation (ISO 10993-1)
- Cleaning and disinfection validation
- Sterilization validation

The joimax® Intracs® em System met all specified criteria and did not raise new safety or performance questions. Based on the performance testing, the joimax® Intracs® em System was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

The testing performed for the joimax® Intracs® em System demonstrated, that the performance of the device is equal to the legally marketed predicate device.