September 20, 2019

Intai Technology Corporation
Shih-Chang Chuang
Manager
No. 9 Jingke Rd., Nantun Dist.,
Taichung City, 40852 TW

Re: K180523
Trade/Device Name: INTAI Surgery Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 21, 2019
Received: August 23, 2019

Dear Shih-Chang Chuang:

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)*
K180523

Device Name
INTAI Surgery Navigation System

Indications for Use *(Describe)*
The INTAI Surgery Navigation System is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery when reference to a rigid anatomical structure, such as the vertebra, can be identified relative to a patient's fluoroscopic or CT imagery. It is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery by means of registering intraoperative 2D fluoroscopic projections to pre-operative 3D CT imagery.
Example procedures include but are not limited to:
Posterior-approach spinal implant procedures, such as pedicle screw placement, within the lumbar region.

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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5. 510(k) Summary

This chapter provides a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

5.1. Submitter's information

Applicant name	INTAI Technology Corporation
Address	No. 9, JingKe Rd., Nantun Dist., Taichung City 40852, Taiwan (R.O.C.)
Telephone number	+886-4-2359-5336
Contact person	Teng-Kuan Tsai
Date prepared	August 15, 2019

5.2. Device information

Device name	INTAI Surgery Navigation System
Trade name	INTAI Surgery Navigation System
Common name	Surgery Navigation System for Spine
Classification name	Orthopedic Stereotaxic Instrument
Classification	Class II (21 CFR 882.4560)
Product code	OLO
Predicate device	Medtronic StealthStation System (K133444) Primary product code: HAW Secondary product code: OLO

5.3. Device description

The INTAI Surgery Navigation System, also known as an image guided system, is comprised of navigation cart, software and its accessories. The system uses wireless optical tracking technology to identify the position of instruments relative to the patient’s anatomy and displays such position on preoperative or intraoperative images of the patient. The images can help guide the surgeons during spinal surgical procedures, such as spinal fusion. The software links all system components and provides several application modules for trajectory planning, image registration, instrument auto-identification and real-time navigation. The system is compatible with the following pedicle screw system and C-arm systems.

5. 510(k) Summary

Compatible Systems	Device Name	510(k) Number
Pedicle screw	Wiltrom spinal fixation system	K172548
C-arm	Siemens Arcadis Varic	K040066
	GE OEC Fluorostar	K043076
	Ziehm Imaging Ziehm Solo	K092438

5.4. Intended use/Indications for use

The INTAI Surgery Navigation System is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery when reference to a rigid anatomical structure, such as the vertebra, can be identified relative to a patient's fluoroscopic or CT imagery. It is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery by means of registering intraoperative 2D fluoroscopic projections to pre-operative 3D CT imagery.

Example procedures include but are not limited to:

Posterior-approach spinal implant procedures, such as pedicle screw placement, within the lumbar region.

5.5. Substantial equivalence comparison

The subject device has the same intended use and technological characteristics as the predicate device. Below is a comparison of the indications for use and technological characteristics of subject device to the predicate device and an assessment of the equivalence of each characteristic. It is shown that technological differences in the subject device do not raise different questions of safety and effectiveness than the predicate device. Therefore, it is concluded that the subject device is substantially equivalent to the predicate device with respect to its indications for use and technological characteristics.

	Subject Device	**Predicate Device**	**Equivalence Assessment**
Device name	INTAI Surgery Navigation System	Medtronic StealthStation System	N/A
Submitter	INTAI Technology Co.	Medtronic Navigation, Inc.	N/A
510(k) number	TBD	K133444	N/A
Primary product code	OLO	HAW	N/A
Secondary product code	N/A	OLO	N/A

5. 510(k) Summary

	Subject Device	Predicate Device	Equivalence Assessment
Indications for use	The INTAI Surgery Navigation System is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery when reference to a rigid anatomical structure, such as the vertebra, can be identified relative to a patient's fluoroscopic or CT imagery. It is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery by means of registering intraoperative 2D fluoroscopic projections to pre-operative 3D CT imagery. Example procedures include but are not limited to: Posterior-approach spinal implant procedures, such as pedicle screw placement, within the lumbar region.	The StealthStation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures, The StealthStation System 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 skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.	**Equivalent** The scope of indications for use of subject device is entirely contained within that of predicate device. The subject device does not have any new indications for use.
Operating principle	The subject device creates a relative position between the patient and 2D C-arm images by means of capturing intra-operative 2D C-arm images of the patient. The relative position between the patient and 3D CT images is established through the registration of intra-operative 2D C-arm images to pre-operative 3D CT images. Subsequently, the subject device can continuously display the relative position of a tracked instrument to a representation of the patient's anatomy. The surgeon can utilize this information as a guide to perform either open or percutaneous spine surgery.	The navigation system creates a translation map between points in the patient anatomy and the corresponding points on radiologic images of the patient. Once this map is established through a process called registration), the software can display the relative position of a tracked instrument to a representation of the patient's anatomy. During surgery, the system tracks the position of specialized surgical instruments in or on the patient anatomy and continuously updates the instrument position on these images either by optical tracking or electromagnetic tracking.	**Equivalent** Both subject device and predicate device are intended to establish the relative position between the tracked instrument and patient's anatomy. The subject device utilizes the same optical tracking system as the predicate device.
Main system components	Optical tracker	Optical and electromagnetic (AXIEM) localization system	**Equivalent** The function of optical tracker, i.e. optical tracking, is equivalent to that of optical localization system. The subject device does not have electromagnetic localization system.
	Navigation cart, including optical tracker, medical panel PC and articulating arms	Staff cart (optical system), including camera and articulating arms, and surgeon cart, including surgeon monitor and articulating arms	**Equivalent** The subject device integrates optical tracker and medical panel PC into a cart. The function of navigation cart is equivalent to that of staff cart and surgeon cart.
	N/A	Keyboard and mouse	**Equivalent** The subject device is controlled through the touch panel of PC.

	Subject Device	Predicate Device	Equivalence Assessment
Main system components	No touch reader	N/A	**Equivalent** No touch reader is used to automatically identify the instruments. User shall manually identify the instrument when using the predicate device.
Patient tracking	Dynamic reference frame (DRF)	Dynamic referencing	**Identical**
Operating system	Windows 7	Debian Linux	**Equivalent** The function of navigation software is successfully verified on Windows' platform, which does not affect its operation.
Modes of operation	**Planning & Navigation Module** 1. Procedure approach (next/last buttons) software for guiding surgical navigation 2. Display of 3D image and multi-planar reconstruction image 3. Localization of patient's position by DRF 4. Anatomical images "Instrument view" at different depths from the viewpoint of instrument tip 5. "Instrument navigation panel" for trajectory planning	**Planning & Navigation Module** 1. Procedure guided software (next/back buttons) with voice prompt, instruction window and task visualization 2. Advanced 3-D modeling capabilities for multiple models or plans 3. PatienTrak dynamic referencing 4. User definable "Look-Ahead" views and display setup 5. Display of the 3D accuracy "Zone" 6. Linear measurement tools in all planes for anatomical sizing 7. 3D guidance view with depth display 8. Screen export as PC compatible JPEG file on CD-ROM	**Equivalent** The subject device does not have those modules incorporated in the predicate device, i.e. module 5, 6 and 8. These modules provide optional functions and do not affect the overall navigation procedure.
	Registration 1. C-arm/CT image registration 2. Minimally invasive surgery for lumbar spine	**Advanced Contour Registration** 1. Registration is achieved by dragging probe across vertebral body 2. For use in cervical, thoracic and lumbar spine 3. Enabling technology for minimal access spine surgery	**Equivalent** Both subject device and predicate device need registration to establish spatial coordinate transformation.
Supported image modalities	CT	CT or MR	**Equivalent** The subject device uses the same CT image modality as the predicate device.

5.6. Non-clinical testing

Verification and validation activities have been completed to provide sufficient assurance that the subject device meets the performance requirements under its indications for use conditions. Below is a summary of all performance tests carried out on the subject device. It is demonstrated that the subject device performs as safely and effectively as the predicate device.

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Test	Description
Cleaning	Cleaning of those reusable accessories is validated in accordance with AAMI TIR30:2011/(R)2016, ASTM F3293-18 and FDA guidance for the “Reprocessing medical devices in health care settings: Validation methods and labeling” issued on March 17, 2015.
Sterilization	Moist heat sterilization of those reusable accessories is validated in accordance with ISO 17665-1:2006.
Repeated Reprocessing	Reliability of those reusable instruments after repeated reprocessing is validated throughout their use-life.
Biocompatibility	Biocompatibility of those accessories that come into contact with patient is evaluated in accordance with FDA guidance for the use of international standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” issued on June 16, 2016 and ISO 10993-1:2009.
Software	Software is verified and validated in accordance with FDA guidance for the content of premarket submissions for software contained in medical devices issued on May 11, 2005 and IEC 62304:2006 + A1:2015.
Electrical Safety	Electrical safety of the system is complied with the requirements of ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012.
Electromagnetic Compatibility	Electromagnetic compatibility of the system is complied with the requirements of IEC 60601-1-2:2014.
Usability	Usability of the system is validated in accordance with ANSI/AAMI HE75:2009/(R)2013, IEC 62366-1:2015 and IEC 60601-1-6:2010 + A1:2013.
Accuracy	Positional accuracy of the system is evaluated in accordance with ASTM F2554-10.
System Performance Validation	Clinical accuracy of the system is validated in cadaver against the acceptance criteria of mean positional error ≤ 3.0 mm and mean trajectory angle error ≤ 3.0 degrees.
Risk Assessment	The effectiveness of all risk control measures is verified in accordance with ISO 14971:2007.

Test	Description
Design Verification	The design output fulfills all design input requirements.
User Needs	The system meets the needs of the end user under simulated use conditions.

5.7. Clinical testing

No clinical testing has been conducted.

5.8. Conclusions

The results of all non-clinical tests demonstrate that the INTAI Surgery Navigation System performs as safely and effectively as the legally marketed predicate device. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the subject device is substantially equivalent to the predicate device with respect to its indications for use and technological characteristics.