August 24, 2022

Remex Medical Corporation
% Sandy Liu
Consultant
Jin Services Co.
9F-1, No13, Lane41, Zhangrong Rd, Sec. 5, North District
Tainan City, 70447
Taiwan

Re: K220348
Trade/Device Name: Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S and SNS-spine2-V
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO

Dear Sandy Liu:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 14, 2022. Specifically, FDA is updating this SE Letter for a typo in the company name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shumaya Ali, M.P.H., OHT6: Office of Orthopedic Devices, 301-796-2356, Shumaya.Ali@fda.hhs.gov.

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

July 14, 2022

Remax Medical Corporation
% Sandy Liu
Consultant
Jin Services Co.
9F-1, No13, Lane41, Zhangrong Rd, Sec. 5, North District
Tainan City, 70447
Taiwan

Re: K220348
Trade/Device Name: Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S and SNS-spine2-V
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 13, 2022
Received: June 13, 2022

Dear Sandy Liu:

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 -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)*
K220348

Device Name
Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S and SNS-spine2-V

Indications for Use *(Describe)*
The Anatase Spine 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

As required by 21CFR 807.92

Applicant Information

Company Name: REMEX MEDICAL CORP.
Company Address: 4F., No. 9, Jingke Road, Nantun Dist.
Taichung, TW 408224, 408224, Taiwan
Telephone: +886-4-23595336
Fax: +886-4-23598875
Contact Person: Shih-Chang Chuang
Summary Updated Date: June 9, 2022

Official Correspondent

Company Name: Jin Services Co.
Company Address: 9F-1, No13, Lane41, Zhangrong Rd, Sec. 5, North Distrit, Tainan City, 70447 Taiwan
Telephone: +886-917535026
Email: contact@fdaclass.com
Contact Person: Sandy Liu, Consultant

Device Name:

Trade Name: Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S and SNS-spine2-V
Classification Name: Stereotaxic instrument
Regulation Number: 882.4560
Product Code: OLO
Device Class: Class 2
Panel: Stereotaxic, Trauma and Restorative Devices (DHT6C)

PREDICATE DEVICE:

K180523, INTAI Surgery Navigation System, Intai Technology Corporation

REFERENCE DEVICE:

K162309 StealthstationS8 System Platforms
K172548 Wiltrom Spinal Fixation System
K132884 PATHFINDER NXT MINIMALLY INVASIVE PEDICLE SCREW SYSTEM
K113529 CD HORIZON VOYAGER SPINAL SYSTEM
K150231 Navigated Disc Prep Instruments

Purpose of Submission: The purpose of this submission is to 1). The Optical Tracker camera "Polaris Spectra" has been discontinued by the supplier, NDI. We add the optional camera "Polaris Vega" to ensure continuous supply of products after clearing the stock of "Polaris Spectra".
2) The calibration process of navigation before surgery become to utilize smoothly via modification of calibration software module and changing the design of calibration instruments.
3) The additional specific screwdrivers are for use with more brands of pedical screws, specifically, Wiltrom™ Spinal Fixation System, PATHFINDER NXT™ Minimally Invasive Pedicle Screw System, and CD HORIZON SOLERA VOYAGER 4.75 SPINAL SYSTEM™.
4) The original trade name "INTAI Surgery Navigation System" was changed after design modification and rename to "Anatase Spine Surgery Navigation System".

Device Description

The Anatase Spine Surgery Navigation System, also known as an Image Guided System, is comprised of a platform, clinical software, surgical instruments, and a referencing system. The system uses optical tracking technology to track the position of instruments in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of a patient. The system helps guide surgeons during spine procedures such as spinal fusion. The software functionality in terms of its feature sets is categorized as imaging modalities, registration, planning, interfaces with medical devices, and views.
The modified Anatase Spine Surgery Navigation System, the subject of these 510(k) applications, introduces software, hardware and instruments modifications to the original Surgery Navigation System cleared in 510(k) K180523.

Intended Use:

The Anatase Spine Surgery Navigation System, Model number: SNS-spine2-S and SNS-spine2-V 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.

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.

Items	**Subject Device** Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S, SNS-Spine2-V	**Predicate Device** INTAI Surgery Navigation System	**Comparison Result**
Submitter	REMEX MEDICAL CORP.	Intai Technology Corporation	N/A
Trade name	Anatase Spine Surgery Navigation System	INTAI Surgery Navigation System	N/A
Model number	SNS-Spine2-S SNS-Spine2-V	SNS-Spine	Note 1
510(k) Number	N/A	K180523	N/A
Device Regulation number	882.4560	882.4560	same
Classification	2	2	same
FDA Product Code	OLO	OLO	same
Indications for Use	The Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S, SNS-Spine2-V SNS-spine2-S and SNS-spine2-V 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	The Intai Technology Corporation 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:	Same

Items	Subject Device Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S, SNS-Spine2-V	Predicate Device INTAI Surgery Navigation System	Comparison Result
	include but are not limited to: Posterior-approach spinal implant procedures, such as pedicle screw placement, within the lumbar region.	Posterior-approach spinal implant procedures, such as pedicle screw placement, within the lumbar region.	
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 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.	Same
Supported image format	DICOM	DICOM	Same
Prescription for use	Yes	Yes	Same
Over the Counter	No	No	Same
Contain any drugs or biologics	No	No	Same
Contain LATEX	Yes	Yes	Same
REUSE	Yes	Yes	Same
Non-Sterile devices provided	Yes	Yes	Same
Operating temperature	10°C - 40°C	10°C - 40°C	Same
Operating humidity	30-75% (RH)	30-75% (RH)	Same
Operating pressure	700hPa-1060 hPa	700hPa-1060 hPa	same
Storage	-10°C - 50°C	-10°C - 50°C	same

Items	Subject Device Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S, SNS-Spine2-V	Predicate Device INTAI Surgery Navigation System	Comparison Result
temperature			
Storage humidity	10-90% (RH)	10-90% (RH)	same
Storage pressure	700 hPa-1060 hPa	700 hPa-1060 hPa	same
Transport temperature	-10°C - 50°C	-10°C - 50°C	same
Transport humidity	10-90% (RH)	10-90% (RH)	same
Transport pressure	700 hPa-1060 hPa	700 hPa-1060 hPa	same
Main system components	● Navigation cart, including optical tracker, No touch reader, medical panel PC and articulating arms ● Image Calibrator with Assembly Kit ● Instrument kits ● Navigation software installation Disc ● User Manual and Software Installation Manual	● Navigation cart, including optical tracker, No touch reader, medical panel PC and articulating arms ● Image Calibrator with Assembly Kit ● Instrument kits ● Navigation software installation Disc ● User Manual and Software Installation Manual	same

*Note 1: The Optical Tracker camera “Polaris Spectra” has been discontinued by the supplier, NDI. We add the optional Tracker camera “Polaris Vega” to ensure continuous supply of products after clearing the stock of “Polaris Spectra”. To identify the different Optical Tracker camera for use in same navigation system, two (2) model numbers are created in the subject devices. “Polaris Vega” is current popular use in similar navigation system, such as reference device “K162309 StealthstationS8 System Platforms”.

Therefore, it is concluded that the subject device (modified from predicate devices) is substantially equivalent to the predicate device with respect to its indications for use and technological characteristics.

Summary of 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.

Test	Description
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, for reference of ISO 11737-2: 2019
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,
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 F2554-18.
Risk Assessment	The effectiveness of all risk control measures is verified in accordance with ISO 14971:2007.
Design Verification	The design output fulfills all design input requirements.

Clinical testing:

No clinical testing has been conducted.

Conclusions:

The conclusion drawn from the non-clinical tests demonstrates that the subject device, the Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S, SNS-Spine2-V, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K180523. Thus, Anatase Spine Surgery Navigation System, Model number: SNS-Spine2-S, SNS-Spine2-V is substantially equivalent to the predicate devices with respect to its intended use, technological characteristics and performance characteristics.