May 1, 2024

Remex Medical Corp.
Wang Cheng-Hsiung
Quality Representative
4F., No. 9, Jingke Road, Nantun Dist.
Taichung, 408209
Taiwan

Re: K233513
Trade/Device Name: Remex Spine Surgery Navigation System II
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 1, 2024
Received: April 1, 2024

Dear Wang Cheng-Hsiung:

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.

Submission Number *(if known)*

K233513

Device Name

Remex Spine Surgery Navigation System II

Indications for Use *(Describe)*

The Remex Spine Surgery Navigation System II, 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:
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.

510(k) Summary

Submitted By	REMEX MEDICAL CORP. 4F., No.9 Jingke Rd., Nantun District, Taichung, TW 408209 Tel. +886-4-23595336 Fax.+886-4-23598875
Contact Person	Chegn-Hsiung Wang Kevin816@mail.intai.com.tw
Date Prepared	May 1, 2024
Device Name	Remex Spine Surgery Navigation System II
Classification Name	Stereotaxic instrument
Regulation Number	882.4560
Product Codes	OLO
Device Class	Class II
Predicate Devices Information	K230738, Anatase Spine Surgery Navigation System (primary) K220348, Anatase Spine Surgery Navigation System K180523, INTAI Surgery Navigation System
Device Description	The Remex Spine Surgery Navigation System II, also known as an Image Guided System, is comprised of a platform, clinical software, surgical instruments, and a referencing system. The system uses wireless 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 are categorized as imaging modalities, registration, planning, interfaces with medical devices, and views.
Indications for Use	The Remex Spine Surgery Navigation System II, 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: Posterior-approach spinal implant procedures, such as pedicle screw placement, within the lumbar region.
Technological Characteristics	The subject devices have the same intended use, indications for use, materials, similar design, fundamental technology, sterilization, and surgical technique as the predicate device, Anatase Spine Surgery Navigation System(K230783). The difference between the subject device and the predicate device is the

upgrade of the system version, and new instruments for corresponding compatible devices. However, these modifications share same function and fundamental technology with predicate device.

Performance Data

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 which should carried out on the subject device to demonstrated that the subject device performs as safely and effectively as the predicate device.

Test	Description
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.
Electrical Safety	Electrical safety of the system is complied with the requirements of ANSI/AAMI ES60601-1:2015/(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 and IEC /TR 60601-4-2.
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.

All existing predicate data previously provided in the predicate 510(k) submission is still applicable, except for the risk assessment and design verification require to re-evaluate. However, the newly added image calibrator and assembly kit share the same testing method as the predicate device and the results of the testing are all pass. Furthermore, the modification of the hardware does not change the operation process of the system as per the User Manual. Therefore, REMEX believes design verification testing demonstrated that the subject devices are substantially equivalent to the predicate devices. Design validation has also been performed and demonstrated that the subject devices performed as intended.

Conclusion

The subject device has been compared to the predicate device with respect to intended use, materials, design features, and performance data. The technological characteristics of the subject device do not raise new type of questions regarding safety and effectiveness. These comparison demonstrate that the Remex Surgery Navigation System II is substantially equivalence to the predicate device.