December 13, 2024

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

Re: K243560
Trade/Device Name: Remex Spine Surgery Navigation Instrument
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 11, 2024
Received: November 18, 2024

Dear Cheng-Hsiung Wang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243560

Device Name
Remex Spine Surgery Navigation Instrument

Indications for Use *(Describe)*
The Remex Spine Surgery Navigation instrument is designed for use with Anatase Spine Surgery Navigation System(K230783) and Remex Spine Surgery Navigation System II(K233513). The Anatase Spine Surgery Navigation System and Remex Spine Surgery Navigation System II are indicated for precise positioning of surgical instruments or spinal implants during general spine 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, with 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.

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

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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	Cheng-Hsiung Wang Kevin816@mail.intai.com.tw
Date Prepared	October 11th, 2024
Device Name	Remex Spine Surgery Navigation Instrument
Classification Name **Regulation Number** **Product Codes** **Device Class**	Stereotaxic instrument 882.4560 OLO Class II
Predicate Devices Information	K233513, Remex Spine Surgery Navigation System II (primary) K230783, Anatase Spine Surgery Navigation System
Device Description	The Remex Spine Surgery Navigation Instrument is designed for use with Anatase Spine Surgery Navigation System (K230783) and Remex Spine Surgery Navigation System II (K233513). The Remex Spine Surgery Navigation Instrument consists of the Nav Awl, Nav Drill Guide, Nav Tap, Nav Screwdriver and Nav Handle. 1. Nav Awl: The subject device is intended to support the surgeon to create an entry point before implanting the screw. 2. Nav Drill Guide: The subject device is intended to assist in drilling holes to a desired depth and ensuring proper orientation. 3. Nav Tap: The subject device is intended to create screw threads. 4. Nav Screwdriver: The subject device is intended to driver the screw into the vertebra. Nav Handle: The subject device is intended to connected with Nav Awl, Nav Tap or Nav Screwdriver for navigation tracking purpose.
Indications for Use	The Remex Spine Surgery Navigation Instrument is designed for use with Anatase Spine Surgery Navigation System (K230783) and Remex Spine Surgery Navigation System II (K233513). The Anatase Spine Surgery Navigation System and Remex Spine Surgery Navigation System II, are 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

<table>
<tr><td></td><td>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.</td></tr>
<tr><td>Technological Characteristics</td><td>The subject devices have the same intended use, same indications for use, same sterilization method, same fundamental technology, and similar materials, similar design as the predicate devices, Anatase Spine Surgery Navigation System (K230783) and Remex Spine Surgery Navigation System II (K233513).

The difference between the subject devices and the predicate devices are the upgrade of the system software version, and new instruments for corresponding compatible devices. However, these modifications share same function and fundamental technology with the predicate devices.</td></tr>
<tr><td>Performance Data</td><td>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.
<table>
<tr><td>Test</td><td>Description</td></tr>
<tr><td>Software</td><td>Software is verified and validated in accordance with FDA guidance for the content of premarket submissions for software contained in medical devices and IEC 62304.</td></tr>
<tr><td>Risk Assessment</td><td>The effectiveness of all risk control measures is verified in accordance with ISO 14971.</td></tr>
<tr><td>Design Verification</td><td>The design output fulfills all design input requirements.</td></tr>
<tr><td>Biocompatibility Evaluation</td><td>The materials that contact with human tissue, blood or bone must be considered for biocompatibility to ensure no rejection, allergic and adverse reactions occur. The subject device 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” and ISO 10993-1.</td></tr>
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The intended use and fundamental technology of the device are identical to the predicate device, and could share the same testing methods as the predicate devices. All the results are passed. Therefore, REMEX believes the testing demonstrated that the subject devices are as safe and effective as the predicate devices.</td></tr>
<tr><td>Conclusion</td><td>The Remex Spine Surgery Navigation Instrument and the predicate devices have the same intended use and have the same or similar technological characteristics. Moreover, the information contained in this submission demonstrates that any differences in their technological characteristics do not raise new issues of safety</td></tr>
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	or effectiveness. Hence, The Remex Spine Surgery Navigation Instrument is substantially equivalent to the predicate devices.