August 20, 2026

Remex Medical Corp.
Jessie Wang
Official Correspondent
4f, #9, Jingke Rd., Nantun District
Taichung, 408209
Taiwan

Re: K262506
Trade/Device Name: Remex Spine Surgery Navigation - Universal Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 20, 2026
Received: July 21, 2026

Dear Jessie 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K262506

Device Name
Remex Spine Surgery Navigation - Universal Instruments

Indications for Use *(Describe)*
The Remex Spine Surgery Navigation – Universal Instruments is intended for use with the Remex Spine Surgery Navigation System II (K251315). The subject device functions as an accessory to the navigation system to support instrument tracking during spine surgical procedures.
The Remex Spine Surgery Navigation System II is 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.
The system is used to conduct procedures such as 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"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

Submitted By	REMEX MEDICAL CORP. 4F., No.9 Jingke Rd., Nantun District, Taichung, TW 408209 Tel. +886-4-23595336 Fax.+886-4-23598875
Prepared by	Jessie Wang jessiewang@remexmed.com
Date Prepared	August 19, 2026
Device Name	Remex Spine Surgery Navigation – Universal Instruments
Classification Name **Regulation Number** **Product Codes** **Device Class**	Stereotaxic instrument 882.4560 OLO Class II
Predicate Devices Information	K251315, Anatase Spine Surgery Navigation System and Remex Spine Surgery Navigation System II (primary)
Device Description	The Remex Spine Surgery Navigation – Universal Instruments is intended for use with the Remex Spine Surgery Navigation System II (K251315). The subject device functions as an accessory to the navigation system to support instrument tracking during spine surgical procedures. The subject devices include newly added navigation instruments, including the Calibration Block, NavGuide Handle_A/B/C, PAK Needle, Universal Instrument Adapter_S/M/L, and Universal Instrument Adapter_DRF-A/B/C. These instruments expand the compatible instruments supported by the existing navigation system. The software was updated to support the newly added instruments. The software update does not change the intended use, fundamental operating principles, or existing navigation workflow of the system.
Indications for Use	The Remex Spine Surgery Navigation – Universal Instruments is intended for use with the Remex Spine Surgery Navigation System II (K251315). The subject device functions as an accessory to the navigation system to support instrument tracking during spine surgical procedures.

<table>
<tr><td></td><td>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.

The system is used to conduct procedures such as: Posterior-approach spinal implant procedures, such as pedicle screw placement, within the lumbar region.</td></tr>
<tr><td>Technological Characteristics</td><td>The subject device has the same intended use and indications for use as the predicate device and has similar technological characteristics and principles of operation.

The differences between the subject and predicate devices are limited to design refinements and software updates to support the additional instruments. These differences do not alter the intended use, principles of operation, or fundamental technological characteristics of the device and do not raise different questions of safety or effectiveness.</td></tr>
<tr><td>Performance Data</td><td>Verification and validation activities have been completed to provide reasonable assurance that the subject device meets the specified performance requirements under its intended conditions of use. The following summarizes the performance testing conducted to demonstrate that the subject device performs as safely and effectively as the predicate devices.

<table>
<tr><td>Test</td><td>Description</td></tr>
<tr><td>Software</td><td>Software verification and validation were performed in accordance with the FDA guidance document for the content of premarket submissions for software contained in medical devices and IEC 62304.

The software update was implemented to support the newly added instruments and does not not alter the intended use, operating principle, or core navigation functions of the navigation system.</td></tr>
<tr><td>Risk Assessment</td><td>The effectiveness of risk control measures was verified in accordance with ISO 14971.</td></tr>
<tr><td>Design Verification</td><td>Design verification activities were performed to confirm that the design outputs satisfy the established design input requirements. The test methods and acceptance criteria are consistent with those applied in the previously cleared submissions, including K251315, K233513, and K243560.</td></tr>
</table>
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	Positional Accuracy	Instrument positional accuracy was conducted in accordance with ASTM F2554-22.

	Navigation accuracy	Navigational accuracy testing was performed under software integration testing using the Remex Spine Surgery Navigation System. The acceptance criteria for navigational accuracy were <2 mm and <2°.
	Biological evaluation	The biological evaluation was conducted in accordance with the principles described in ISO 10993-1:2018.
	The subject device maintains the same intended use and fundamental operating principles as the predicate devices. The differences between the subject device and predicate devices are limited to the addition of new instruments and the associated software update required to support these instruments. The verification and validation methods were selected based on the characteristics of the device changes, and all acceptance criteria were met. Based on the performance data, the subject device is considered as safe and effective as the predicate devices.	
Conclusion	The Remex Spine Surgery Navigation – Universal Instruments and the predicate devices have the same intended use and have the same or similar technological characteristics. The differences between the subject device and the predicate devices are limited to the addition of new instruments and the associated software update to support these instruments. The information provided in this submission demonstrates that these differences do not raise different questions of safety or effectiveness. The verification and validation activities were completed, and all predefined acceptance criteria were met. No additional safety or effectiveness concerns were identified. Therefore, the Remex Spine Surgery Navigation – Universal Instruments is substantially equivalent to the predicate devices.	