July 5, 2024

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

Re: K241625
Trade/Device Name: Anatase Navi Disposable Instrument
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: June 6, 2024
Received: June 6, 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, MPH
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.

Submission Number *(if known)*

K241625

Device Name

Anatase Navi Disposable Instrument

Indications for Use *(Describe)*

The Anatase Navi Disposable Instrument is designed for use with Anatase Spine Surgery Navigation System and Remex Spine Surgery Navigation System II. 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 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.

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

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K241625
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	June 6th, 2024
Device Name	Anatase Navi Disposable Instrument
Classification Name	Stereotaxic instrument
Regulation Number	882.4560
Product Codes	OLO
Device Class	Class II
Predicate Devices Information	K220348, Anatase Spine Surgery Navigation System (Primary Predicate) K180523, INTAI Surgery Navigation System (Additional Predicate Device) K233513, Remex Spine Surgery Navigation System II (Additional Predicate Device)
Device Description	The Anatase Navi Disposable Instrument is designed for use with Anatase Spine Surgery Navigation System and Remex Spine Surgery Navigation System II. The Guiding awl is intended to support the surgeon to create an entry point before implanting the screw. The Spine pin with DRF-D and MIS LOC with DRF are both intended to fix the DRF on the vertebra by boned pins or the clamp. Once the DRF is fixed on the vertebra, the system can track the position of the patient's vertebra and instruments.
Indications for Use	The Anatase Navi Disposable Instrument is designed for use with Anatase Spine Surgery Navigation System and Remex Spine Surgery Navigation System II. 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 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 device has the same intended use, indications for use, design, fundamental technology, and surgical technique as the instrument in the predicate device, Anatase Spine Surgery Navigation System.

The difference between the subject device and the predicate device is the fabricated material, package, and sterilization method. The package and sterilization are changed because the subject device is intended to be single-use instead of repeat-use as the predicate device. However, these modifications are tested accordingly to demonstrate that the subject device is as safe and effective as the 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 carried out on the subject device to demonstrate that the subject device performs as safely and effectively as the predicate device.

Test	Description
Package	The package related to the sterile barrier must be validated to confirm the safety and effectiveness of the medical device. Validation is confirmed by the demonstration of sterile barrier integrity over the intended shelf-life.
Sterilization	The subject device is provided EO sterilized. The sterilization process must be controlled and validated in compliance with ISO 11135 to ensure the effectiveness of the sterilization process.
Biocompatibility Evaluation	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" issued on June 16, 2016 and ISO 10993-1:2009.
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.

The design of the device is identical to the predicate device. However, the change from repeat-use to single-use triggers sterilization and package change which require validation to ensure the sterile barrier and sterile parameter can fulfill its intended purpose. The tests in the above

	table are all tested in compliance with FDA-recognized standards, and all the results are passed. Therefore, REMEX believes the testing demonstrated that the subject devices are as safe and effective as the predicate devices.
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 types of questions regarding safety and effectiveness. These comparisons demonstrate that the subject device is substantially equivalent to the predicate device.