May 23, 2025

Brain Navi Biotechnology Co., Ltd.
% Feng-Yu Lee
Principal Regulatory Consultant
Elite BioMedical Consulting, Inc.
29122 Rancho Viejo Road, Suite 212
San Juan Capistrano, California 92675

Re: K242575
Trade/Device Name: Stereotaxic Guiding Surgical Devices, NaoTrac S
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: April 25, 2025
Received: April 25, 2025

Dear Feng-Yu Lee:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.05.23 13:23:26 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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)*
K242575

Device Name
Stereotaxic Guiding Surgical Devices (NaoTrac S)

Indications for Use *(Describe)*
Stereotaxic Guiding Surgical Devices, NaoTrac S is intended for the spatial positioning and orientation of instrument holder or instrument tool to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode). The device is indicated for any neurosurgical procedure in which the use of stereotactic surgery may be appropriate.

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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Brain Navi Biotechnology

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K242575

1. Submitter's Identification:

Brain Navi Biotechnology
No. 66-1, Shengyi 5th Rd., Zhubei City, Hsinchu County 302041, Taiwan
Contact Person: Shally Lu
Phone Number: +886-3-6579438

c/o Elite BioMedical Consulting, Inc.
29122 Rancho Viejo Road, Suite 212
San Juan Capistrano, CA 92675 (US Branch)
Contact Person: Feng-Yu Lee
Phone Number: 1-949-218-0929
Fax Number: 1-949-218-0928
Date Summary Prepared: May 23, 2025

2. Name of the Device:
Stereotaxic Guiding Surgical Devices, NaoTrac S

3. Common or Usual Name: Neurological Stereotaxic Instrument

Product Code	Classification	Regulation Section	Panel
HAW; Neurological Stereotaxic Instrument	Class II	21 CFR 882.4560	Neurology

4. Device Description:

Stereotaxic Guiding Surgical Devices, NaoTrac S is a robotized platform for the guidance of neurosurgical instruments compatible with the diameter of instrument adaptor provided by Brain Navi Biotechnology Co., Ltd.
Stereotaxic Guiding Surgical Devices, NaoTrac S is composed of a compact robotic arm and display screen mounted on a wheeled trolley. Different types of instruments may be attached to the end of the arm and changed according to the requirements of the procedure to be completed.

The display screen permits to ensure the communication between NaoTrac S and its user by indicating the realizable actions as well as by proposing various commands. NaoTrac S is an aid for locating anatomical structures in either open or percutaneous procedures.

5. Indications for Use:

Stereotaxic Guiding Surgical Devices, NaoTrac S is intended for the spatial positioning and orientation of instrument holder or instrument tool to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode). The device is indicated for any neurosurgical procedure in which the use of stereotactic surgery may be appropriate.

6. Predicate Device Information:

Stereotaxic Guiding Surgical Devices, NaoTrac S is substantially equivalent to the brand of ROSA ONE Brain Application noted as 6.1.

6.1
Name: ROSA ONE Brain Application
Device Company: Medtech S.A
510(K) Number: K182417

7. Comparison to Predicate Devices:

Device	ROSA ONE® Brain Application v 3.1 (Predicate Device: K182417)	Stereotaxic Guiding Surgical Devices, NaoTrac S (Subject device)	Comparison Analysis
Device description and indications for use			
General device description	Computer controlled electromechanical arm providing guidance of neurosurgical instruments	Computer controlled electromechanical arm providing guidance of neurosurgical instruments	Identical
Indications For Use	The device is intended for the spatial positioning and orientation of instrument holders or tool guides to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode, endoscope). The device is indicated for any neurosurgical procedure in which the use of stereotactic surgery may be appropriate.	Stereotaxic Guiding Surgical Devices, NaoTrac S is intended for the spatial positioning and orientation of instrument holder or instrument tool to be used by neurosurgeons to guide standard neurosurgical instruments (biopsy needle, stimulation or recording electrode). The device is indicated for any neurosurgical procedure in which the use of stereotactic surgery may be appropriate.	Similar with the deletion of with endoscope
Where used	Neurosurgical operating room	Neurosurgical operating room	Identical
User	Neurosurgeon	Neurosurgeon	Identical
Anatomical site	Head	Head	Identical

Principle of Operation	- Pre & intraoperative images - Surgical planning - Patient registration - Guidance of instruments	- Planning - Patient Registration - Surgical operation	Similar operating procedures with different name of the procedures
Preoperative images and Surgical planning			
Images type	3D MRI / CT	3D MRI / CT	Identical
DICOM compliance	Yes	Yes	Identical
Merge images (multimodality image fusion capability)	Yes	No	Different, but not affect safety and effectiveness
Integrated planning software	ROSANNA BRAIN (Medtech)	NaoTrac S Software (Brain Navi)	Different software
Define regions of interest (ROI)	Yes	No	Different, but not affect safety and effectiveness
Trajectory planning parameters	Entry point, target point, length of the instrument, diameter, name, color	Entry point, target point, length of the trajectory, diameter, name, color.	Identical
Trajectory definition (Endoscopy module)	Parameters for planning trajectories: entry point, target point, length of the instrument, diameter, name, security radius (10mm by default), security aperture (10° by default)	No	Different, but not affect safety and effectiveness
Save/load planning	Yes	Yes	Identical
Patient registration			
Localization means	Robotic Arm absolute encoders	Robotic Arm absolute encoders	Identical
Controller	Axis controller for each joint Kinematic transformation between the Cartesian space and joint space Supervisor module	Axis controller for each joint Kinematic transformation between the Cartesian space and joint space Supervisor module	Identical
Head holder	- Required (MAYFIELD/DORO head holder is recommended). - The robotic stand is rigidly secured to the head holder or to the stereotactic frame, providing a fixed reference between the registration phase and the surgical phase to avoid any mechanical movement.	- Required (MAYFIELD /DORO head holder is recommended). - The Moving Detector, which includes Tag S, Tag Support Arm, and IR Module, can detect the movement of a patient. - The IR Module fixed in the trolley - Tag S, Tag Support Arm are secured on the head holder.	Different Detect patient movement without fixed secured
Patient immobilization	Yes - The device is attached to the head holder or the frame via an adaptor.	- Required (MAYFIELD /DORO head holder is recommended). - The Moving Detector, which includes Tag S, Tag Support Arm, and IR Module, can detect the movement of a patient. - The IR Module fixed in the Trolley	Different Detect patient movement without fixed secured

		- Tag S, Tag Support Arm are secured on the head holder.	
Patient Registration methods	- Fiducial makers (skin or bone) - Optical registration device - Stereotactic frame (fiducials mounted on the frame)	- Surface Matching (Optical registration device)	Different in registration algorithm
Fiducial markers registration with pointer probe	Yes	No	Different in registration algorithm
Surface matching registration with optical distance sensor	Yes	Yes	Similar method, but with different registration procedures
Laser class for optical registration	Class 2 laser Wavelength – 658 nm, Maximum output – 1mW (complies with 21 CFR 1040.10)	Blue LED light, Wavelength 465nm	Different in optical source
Cooperative movement	Yes	Yes	Identical
Accuracy verification on anatomical landmarks	Yes	Yes	Identical
Guidance of instruments			
Instrument fixation	Instruments are mounted onto robotic arm's flange	Instruments are mounted onto Insulator	Different mounted part but still on robotic arm's flange
Instrument Calibration Method	Factory calibration	Factory calibration	Identical
Instruments	Instrument holder, endoscope holder and adaptors, optical sensor	Instrument Holder S, Instrument Adaptor, Catheter Adaptor, SEEG Adaptor, Reference Stylus	Different, but not affect safety and effectiveness
Image-guided	Yes	Yes	Identical
Real time display of the instrument position	Yes	Yes	Identical
Provide guidance for surgical instruments	Yes	Yes	Identical
Instrument guide position adjustment	Automatic (robotized)	Automatic (robotized)	Identical
Surgeon carries out final gesture through the instrument guide with traditional surgical instrument	Yes—through the instrument guide	Yes—through the instrument guide	Identical
Associated equipment	- Pointer probe - Standard tool holder	- Instrument Holder S Set ■ Instrument Holder S	Different, but not affect

	- Endoscope holder - Microdrive holder - Optical sensor - Fiducial markers - Head holder - Leksell frame registration plates - CRW Frame	■ Thumb Screw of Instrument Holder ■ Set Screw of Instrument Holder ■ Instrument Adaptor ■ Catheter Adaptor ■ SEEG Adaptor ■ Pin Screw of Instrument Adaptor - Reference Stylus - Moving Detector ■ Tag S ■ Tag Support Arm ■ IR module* - Foot Controller - USB Mouse - Surgical Equipment Drape ■ Display Screen Drape ■ Robotic Arm Drape ■ Tape - Instrument Registration Platform Cover(PET)	safety and effectiveness. *Since the IR Module is fixed on the Trolley, only Tag S and Tag Support Arm need to be packaged.
Specifications			
Energy Source	- 220-240 Vac, 50/60Hz, 4 A (for Europe) - 115 Vac, 50/60Hz, 6 A (for USA/Canada) - 100 Vac, 50/60Hz, 8 A (for Japan)	- 100-120 Vac, 50/60Hz, 6A - 220-240 Vac, 50/60Hz, 3A	Different, but not affect safety and effectiveness
Operation environmental conditions	- Temperature range of + 10°C to + 35°C - Humidity range of 8% to 93% (without condensation) - Atmospheric pressure range of 800 hPa to 1060 hPa	- Ambient temperature range of + 10°C to + 40°C - Relative humidity range of 30% to 85% - Atmospheric pressure range of 800 hPa to 1013 hPa	Different, but not affect safety and effectiveness
Transport and storage environmental conditions	- Temperature range of -5°C to + 50°C - Humidity range of 8% to 93% (without condensation) - Atmospheric pressure range of 800 hPa to 1060 hPa	- Ambient temperature range of 0°C to + 60°C; - Relative humidity range of 30% to 85%, including condensation;	Different, but not affect safety and effectiveness
Device dimensions	- 121 cm (L) x 65 cm (W) x 102 cm (H) - 121 cm (L) x 65 cm (W) x 150 cm (H) (Include robotic arm)	- 112 cm (L) x 65 cm (W) x 110 cm (H) - 112 cm (L) x 65 cm (W) x 215 cm (H) (Include robotic arm)	Different, but not affect safety and effectiveness
Main Components	Robotic Stand: - 6-axis robotic arm - The touchscreen for operating the device - The immobilization system - The vigilance device - The computer and software	Trolley: - 6 axis robotic arm - Computer and software - Display Screen - Face Camera - Moving Detector - Instrument Registration Platform - Foot Pedal - Jack system	Different, but not affect safety and effectiveness

Robotized arm	- Degree of freedom:6 rotating joints; absolute encoders - Payload:3.7kg - Reach range:920 mm - Pose repeatability: ±0.03 mm	- Degree of freedom:6 rotating joints; absolute encoders - Payload:5.0kg - Reach range:850 mm - Pose repeatability: ±0.1 mm	Different, but not affect safety and effectiveness
Device mobility	Yes - Mobile stand with wheels, immobilized with 4 stabilization feet	Yes - Mobile stand with wheels, immobilized with 4 stabilization feet (Jack System)	Identical
Sterility	Non-sterile and sterile instruments Disposable sterile drapes for the robotic arm and touch screen	Non-sterile and sterile instruments Disposable sterile drapes for the robotic arm and touch screen	Identical
Vigilance system	Yes -foot pedal	Yes -Foot Controller	Identical
Software	- ROSANNA v3.1.0 - The software provides three major functionalities: Planning, Navigation and Surgery.	- NaoTrac S Software ver.1.1.0 - Our software provides three major functionalities: Planning, Navigation and Surgery.	Different, but not affect safety and effectiveness
Device performance: application accuracy	- < 2 mm (Euclidean distance)	- < 2 mm (Euclidean distance)	Identical
Device performance: Angular error	- < 2 degrees	- < 2 degrees	Identical

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Accuracy Testing

The accuracy tests include systematic accuracy, tested according to internally defined methods. This test comprises two assessments: position accuracy and angular accuracy.

Overall Accuracy Performance Validation	Positional Error (mm)			Trajectory Angle Error (degrees)		
	Mean	Standard Deviation	99% Confidence Interval	Mean	Standard Deviation	99% Confidence Interval
NaoTrac S	1.13	0.38	1.31	0.64	0.37	0.82

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the NaoTrac S. The system complies with the IEC 60601-1 and ANSI AAMI ES 60601-1 standards for safety and the IEC 60601-1-2 for EMC.

Software Verification and Validation

Software tests were conducted to satisfy the requirements of the FDA guidance document for the Content of Premarket Submissions for Software Contained in Medical Devices and IEC 62304 Standard (Medical Device Software - Life Cycle Process). The software was considered as a "major" level of concern since a failure of the software could result in serious injury or death to the patient.

Software verification activities were performed during the "Design, coding & testing" and "Verification" phases of software lifecycle. Outputs generated during these phases include:

- Code guidelines
- Unit test reports
- Integration test reports
- System test reports
- Verification test reports

Cleaning and Sterilization Validation for Re-use Accessories

Brain Navi Biotechnology Co., Ltd. conducted a cleaning validation in compliance with the FDA Guidance Document on “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,’”, AAMI TIR30, and AAM TIR12 Technical Report.

Furthermore, the sterilization validation was executed per ISO 17665-1, ISO 17664, ISO 11737-1, ISO 11737-2, and AAMI TIR12 Technical Report using two cycles.

Sterilization Validation for Single-use Accessories

The sterilization validation of the single-use accessories was conducted in compliance with ISO 11137-1. Moreover, the shelf-life and packaging testing of the accessories was carried out in compliance with the following standards: ASTM F1980 and ISO 11607-1.

9. Discussion of Clinical Tests Performed:

Clinical data were not required to support the safety and effectiveness of NaoTrac S. All validation was performed based on non-clinical performance tests.

10. Conclusions:

Results of performance evaluation of Stereotaxic Guiding Surgical Devices, NaoTrac S demonstrate that the device is substantial equivalence to the predicate device, ROSA ONE Brain Application.