October 26, 2026

Medivis, Inc.
Amy Lynn, Chief Compliance Officer
174 5th Ave.
Suite 200
New York, New York 10010

Re: K261997
Trade/Device Name: NeuroAlign
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: October 1, 2026
Received: October 1, 2026

Dear Amy Lynn:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.10.26 13:50:55 -04'00'

for Ryan Trombetta, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261997

Please provide the device trade name(s).

NeuroAlign

Please provide your Indications for Use below.

The Medivis NeuroAlign device is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical instruments employed by surgeons. This device is specifically intended for cranial surgery, where reference to a rigid anatomical structure can be identified, without the need for a frame or fixation of a navigated instrument guide to the patient. The system is intended for use in various surgical settings, including operating rooms, intensive care units, and interventional procedure suites.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) SUMMARY

Prepared in accordance with 21 CFR 807.92

Submission Number	K261997
Submitter	Medivis, Inc.
Address	174 5th Ave, Suite 200 New York, NY 10010 United States
Contact	Amy Lynn Phone: (954) 600-8299 Email: amy@medivis.com
Date Prepared	September 29, 2026

1. Device Information

Trade Name	NeuroAlign
Common Name	Stereotaxic instrument
Classification Name	Neurological Stereotaxic Instrument
Regulation	21 CFR 882.4560
Regulatory Class	Class II
Product Code	HAW

2. Predicate Device

NeuroAlign Software, K231897 (product code HAW).

3. Device Description

The NeuroAlign system is a software-based image-guided surgical navigation system intended for use during cranial surgical navigation procedures. The system assists surgeons by providing real-time visualization of tracked surgical instruments relative to pre-operative patient imaging, enabling localization and navigation during neurosurgical procedures.

The system consists of NeuroAlign software installed on a workstation computer, an optical infrared tracking system, patient reference arrays, tracked surgical instruments, and an optical see-through head-mounted display (HMD). NeuroAlign imports Digital Imaging and Communications in Medicine (DICOM) datasets, including computed tomography (CT) and magnetic resonance imaging (MRI) studies, to generate three-dimensional patient anatomy and navigation datasets. Before navigation, patient anatomy is registered to the image dataset using established stereotactic registration techniques. During surgery, the active tracking system tracks passive reflective fiducial markers attached to the patient reference array and surgical instruments. NeuroAlign calculates the spatial relationship between tracked instruments and registered patient anatomy and displays instrument position in real time on multiplanar and three-dimensional views.

The scientific principles underlying NeuroAlign are stereotactic image-guided navigation and optical tracking. Infrared stereoscopic cameras detect fiducial markers attached to rigid-body reference arrays and surgical instruments. Optical triangulation determines the three-dimensional position and orientation of tracked objects, and NeuroAlign registers these coordinates to the patient's imaging dataset to provide real-time navigation.

NeuroAlign provides functionality to:

- Import and manage patient CT and MR image datasets;
- Generate three-dimensional anatomical reconstructions;

- Perform patient registration and navigation setup;
- Display axial, sagittal, coronal, and three-dimensional navigation views;
- Track surgical instruments and patient reference arrays in real time; and
- Monitor system and optical tracking status throughout the procedure.

The principal components include:

- NeuroAlign software;
- Medical workstation computer;
- Optical infrared tracking camera;
- Passive reflective markers and patient reference arrays;
- Tracked surgical instruments; and
- Optical see-through HMD.

NeuroAlign supports two tracking modes. In HMD tracking mode, the HMD performs stereotactic tracking and displays navigation information in the manner cleared in K231897. In external camera tracking mode, the Atracsys spryTrack 300 performs stereotactic tracking, the workstation provides the navigation display, and the HMD may be used as an optional adjunct display. The system uses one tracking source at a time; tracking data from the HMD and external camera are not combined or fused.

This submission includes two modifications to the previously cleared NeuroAlign system. First, compatibility has been added with the Atracsys spryTrack 300 as an alternative optical tracking option. The spryTrack 300 is a stereoscopic infrared optical tracking camera that detects passive reflective fiducial markers and communicates tracking information to the NeuroAlign workstation through a wired USB interface.

Second, reusable surgical accessories have been added: the 100 mm Autoclavable Localizer (PN 1002-LOC100-01), Mayfield Reference Array (PN 2002-REF01-01), and Cranial Tray (PN 2002-TRAY01-01). These accessories support patient registration, referencing, localization, and image-guided navigation and are intended to be reprocessed by steam sterilization between uses. Reprocessing instructions and cleaning and steam sterilization validation are included in the submission.

The Disposable Localizer, Catheter Clip, and Forehead Reference Marker cleared in K231897 have not changed. Their new catalog numbers are administrative product-identification updates only.

No Predetermined Change Control Plan (PCCP) is included in this submission. No online videos or external web-based review resources are included as part of this submission.

4. Indications for Use

The Medivis NeuroAlign device is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical instruments employed by surgeons. This device is specifically intended for cranial surgery, where reference to a rigid anatomical structure can be identified, without the need for a frame or fixation of a navigated instrument guide to the patient. The system is intended for use in various surgical settings, including operating rooms, intensive care units, and interventional procedure suites.

5. Comparison of Intended Use and Technological Characteristics

The intended use and clinical scope of the subject NeuroAlign device remain the same as those of the predicate NeuroAlign device (K231897). The subject and predicate devices share the same intended users, anatomical site, fundamental scientific technology, and core operating principles. Both use pre-operative medical imaging datasets, optical tracking technology, fiducial markers, and software-based stereotactic navigation to provide real-time localization of surgical instruments relative to patient anatomy.

Both devices utilize:

- Pre-operative DICOM medical imaging datasets;
- Optical infrared tracking technology;
- Fiducial-based instrument localization;
- Real-time stereotactic navigation software;
- Three-dimensional anatomical visualization; and
- Workstation-based image processing and display functionality.

The subject device adds compatibility with the Atracsys spryTrack 300 external optical infrared tracking camera and the reusable surgical accessories identified above. These changes do not alter the intended use, intended users, anatomical region, operating principles, or fundamental scientific technology and do not raise different questions of safety or effectiveness compared with the predicate device. Associated software updates support the added components while maintaining the established navigation workflow, registration methodology, and intended operating environment.

6. Performance Data

Nonclinical Testing

Nonclinical bench testing evaluated overall procedural accuracy of NeuroAlign using the Atracsys spryTrack 300 external optical tracking camera under simulated clinical-use conditions. Testing encompassed the complete cranial navigation workflow, including image loading, trajectory planning, instrument calibration, patient registration, and user-guided navigation.

Five users completed five repetitions of five predefined trajectories, resulting in 125 trials. A validated contactless optical coordinate measurement system established ground-truth measurements. Positional and angular errors were evaluated against predefined system-level acceptance criteria of mean positional error ≤2 mm and mean angular error ≤2 degrees.

The testing was performed using software version 2.0, the branch that introduced the Atracsys external-camera tracking functionality. Changes between version 2.0 and the current version 3.1.0 did not modify the tracking algorithms, registration methodology, coordinate transformations, accuracy calculations, or other functions affecting navigational accuracy. Software verification and regression testing confirmed that the tested navigational performance remains representative of version 3.1.0.

Software verification and validation, system integration testing, regression testing, and validation of the reusable surgical accessories were also conducted. Cleaning and steam sterilization validation support reuse of the added autoclavable accessories. The Atracsys spryTrack 300 component manufacturer's IECEE CB Test Certificate CH-11446 documents conformity to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020.

Clinical Testing

Clinical testing was not required to support the determination of substantial equivalence.

7. Conclusion

The nonclinical test results demonstrate that NeuroAlign, including use with the Atracsys spryTrack 300 external optical tracking camera and the added reusable surgical accessories, meets its predefined performance requirements. The technological differences from the predicate device do not raise different questions of safety or effectiveness. The subject device is therefore as safe and effective as, and performs as well as, the legally marketed predicate device, NeuroAlign (K231897).