October 21, 2025

Medivis, Inc.
Amy Lynn
Chief Compliance Officer
920 Broadway, 16th Floor
New York, New York 10010

Re: K231897
Trade/Device Name: NeuroAlign software
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: December 20, 2024
Received: December 23, 2024

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.

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: 2025.10.21 12:04:47 -04'00'

Adam 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231897

Device Name
Medivis NeuroAlign

Indications for Use *(Describe)*
The Medivis NeuroAlign device is stereotaxic image guidance system intended to be used with the Microsoft HoloLens headset 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.

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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Medivis, Inc.
NeuroAlign

510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	Medivis, Inc. 920 Broadway, 16th floor, New York, NY 10010 (954) 600 - 8299
Correspondent Contact Information:	Amy Lynn 920 Broadway, 16th floor, New York, NY 10010 (954) 600 - 8299
Device Common Name:	Neurological Stereotaxic Instrument
Device Regulation & Name:	21 CFR 882.4560 Stereotaxic instrument
Classification & Product Code: 510(k) Number:	Class 2 HAW K231897
Device Proprietary Name:	NeuroAlign

Predicate Device Information:

Predicate Device:	VECTORVISION CRANIAL
Predicate Device Manufacturer:	BRAINLAB AG
Predicate Device Common Name:	Neurological Stereotaxic Instrument
Predicate Device Premarket Notification #	K092467
Predicate Device Classification & Name	Class 2 Stereotaxic instrument
Predicate Device Classification & Product Code:	Class 2 HAW

B. Date Summary Prepared

October 21, 2025

C. Description of Device

The Medivis NeuroAlign device is a software application that processes and visualizes anatomical images for surgical navigation. It works in conjunction with off-the-shelf hardware and surgical instruments, including an IGS workstation, touchscreen monitor, and a 3D tracking system, along with IR trackable surgical instruments. The device uses pre-acquired patient data, which can be transferred from the hospital's PACS or local files. It operates with a network-based software interface for data downloading and supports image upload for custom visualization. The device's data transfer is unidirectional. It provides various image display options and manipulation features, primarily controlled through the touchscreen monitor. An HMD serves as an adjunct heads-up display and functions as an

optical 3D tracking component for patient and surgical tool localization. The device registers patient data to the surgical environment through IR tracking, but it does not overlay data onto the surgical site. It cannot integrate with intra-operative image sources like surgical microscopes or ultrasound devices.

D. Indications for Use

The Medivis NeuroAlign device is stereotaxic image guidance system intended to be used with the Microsoft HoloLens headset 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.

Contraindications

The Medivis NeuroAlign device should not be used to overlay images over patient anatomy, as this may interfere with the surgeon's visualization and potentially lead to patient harm due to inaccurately guided instruments. Overlay functions, including those described herein, should not be utilized during surgical procedures. Failure to adhere to this contraindication may result in compromised surgical outcomes.

E. Comparison of the Technological Characteristics

The Medivis NeuroAlign (subject device) and the predicate device share the same technological characteristics, as defined by FDA guidance, which include materials, energy sources, overall device design, and key technological features. In terms of materials, both devices are proprietary software applications that utilize off-the-shelf computer hardware and IR tracking instrumentation. Both devices operate on off-the-shelf IT equipment, serving as the energy source and contributing to the device design. Specifically, regarding the incorporation of the HMD, the technological rationale is provided herein.

First, both devices use monitors for streaming the software application output. The subject device has two monitors compared to the predicate's single monitor. The subject device and predicate both have traditional monitors. In addition, the HMD is used as an adjunct heads-up display monitor. It does not replace the traditional monitor already present in the subject device. The use of the HMD as an additional display technology does not change the core use of the IGS workstation which is equipped with a touchscreen monitor as the primary display as found in the predicate device. The touchscreen monitor is consistently available to the user and remains the primary input device, exactly like the predicate device. This ensures that the HMD serves as an adjunct heads-up display, which can be used to enhance the surgeon's situational awareness without displacing the established standard of care. Its role is complementary and non-disruptive to the surgeon's workflow. Neither the subject device nor the predicate is intended for diagnostic review of medical images and the subject device's incorporation of the HMD as a heads-up display remains consistent with this non-diagnostic purpose. Moreover, the absence of virtual information overlaid in the surgical field eliminates the possibility of inadvertent hand gesture interactions during a procedure. The HMD's function within the subject device is limited to streaming data from the workstation,

and it does not process or convert patient images. The processing of patient images and their visualization is executed on the workstation just like it is on the predicate device. This fact ensures that the HMD's role is that of a passive heads-up display technology, aligned with the predicate's display function.

Second, both the subject and predicate device rely on infrared tracking technology. The predicate device utilizes a fixed camera while the subject device leverages the HMD's IR camera. The specific operating principles are identical between these two components; only their form factor differ. The difference between using a fixed camera and HMD that both operate in the exact same way is the basis for the justification for substantially equivalent technology. Both the fixed cameras and the Microsoft HoloLens 2 share the same technological characteristics and purpose. They are general components that can be integrated into medical devices and are not, by themselves, medical devices. Neither component is designed for a specific application, as their primary role is to facilitate the precise localization and tracking of instruments in real-time during surgical procedures.

When leveraged as a component to the subject device, the IR cameras on the HoloLens 2 have the same technological characteristics of the camera leveraged in the Brainlab predicate device. Optical tracking via infrared light on the fixed camera or the HoloLens 2 IR camera work exactly the same. The tracking data is communicated to the software application (i.e., Medivis NeuroAlign or Brainlab Vector Vision) for real-time visualization and navigation of the surgical instruments relative to the patient image sets.

In summary, both devices share common features, notably the presence of a touchscreen monitor within the IGS workstation, which serves as the user's primary input interface. Additionally, both devices employ optical tracking through the utilization of infrared light, with the underlying scientific method for IR-based optical tracking remaining consistent between them. The specific manner in which the HMD is integrated as a component within the subject device upholds the same technological characteristics as observed in the predicate device. Consequently, the technological characteristics remain consistent and identical between the two devices.

F. Summary of Supporting Data

Summary Table

Test Name	Test Description	Results
Tracking Accuracy	Per ASTM F2554-18	Successfully met predetermined acceptance criteria
Recognition of 3rd Party Reference Arrays	Compatibility of 3rd party instruments	Successfully met predetermined acceptance criteria
Adhesive Longevity	Reference marker adhesive	Successfully met predetermined acceptance criteria

Hand Gesture	User interface of the HoloLens2 HMD specific to commands activated by hand gestures	Successfully met predetermined acceptance criteria
End to End Latency	Motion-to-photon latency of the tracking module of NeuroAlign	Successfully met predetermined acceptance criteria
Ground Truth Accuracy	Overall procedural accuracy of the device with a user in the loop, by establishing the overall accuracy values and ensuring that the overall system error remains within 2mm and 2 degrees	Successfully met predetermined acceptance criteria

G. Discussion of Performance Testing

The passing results of the performance tests provide objective evidence that the design output specification satisfy the design input requirements. The passing results of the performance tests provide objective evidence that the software specifications conform to the intended users' needs and intended use of the device.

H. Conclusion

In conclusion, despite the minor differences, they do not constitute significant changes to the intended use or technological characteristics of the devices. Thus, the Medivis subject device has been established to be as safe and effective as the legally marketed predicate device, reinforcing their substantial equivalence.