January 3, 2025

Inventis S.r.l.
Elena Tormen
Quality& Regulatory Manager
Corso Stati Uniti 1/3
Padova, 35127
Italy

Re: K242726
Trade/Device Name: Synapsys VHIT
Regulation Number: 21 CFR 882.1460
Regulation Name: Nystagmograph
Regulatory Class: Class II
Product Code: GWN
Dated: December 5, 2024
Received: December 5, 2024

Dear Elena Tormen:

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,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*

K242726

Device Name

Synapsys VHIT

Indications for Use *(Describe)*

The Synapsys VHIT is a medical device designed to assess the vestibular-ocular-reflex (VOR) by measuring, recording, displaying, and analyzing eye and head movements.

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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510(k) Summary

Prepared on: 2024-12-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	INVENTIS S.r.l.
Applicant Address	Corso Stati Uniti 1/3 Padova 35127 Italy
Applicant Contact Telephone	+39 0498962844
Applicant Contact	Mrs. Elena Tormen
Applicant Contact Email	quality@inventis.it

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Synapsys VHIT
Common Name	Nystagmograph
Classification Name	Nystagmograph
Regulation Number	882.1460
Product Code(s)	GWN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K151504	ICS Impulse	GWN

Device Description Summary

21 CFR 807.92(a)(4)

Synapsys VHIT (Video Head Impulse Test) allows to assess the vestibular-ocular-reflex (VOR) by measuring, recording, displaying, and analyzing eye and head movements.
Synapsys VHIT does not require the patient to wear goggles, since it consists of a remote camera placed 90 cm from the subject, framing the subject's eyes and head. The device features real-time eyes detection and tracking, thanks to a built-in infrared illuminator that lights up the subject. Head displacements are retrieved using software tracking algorithms that extract motion data from real time images recorded by the camera.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Synapsys VHIT is a medical device designed to assess the vestibular-ocular-reflex (VOR) by measuring, recording, displaying, and analyzing eye and head movements.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use of Synapsys VHIT device and the predicate device (ICS Impulse) are the same.

Technological Comparison

21 CFR 807.92(a)(6)

Synapsys VHIT has different technological characteristics from the predicate device.
Predicate device Natus ICS Impulse consists of head mount goggles which measure the velocity of the head through an accelerometric sensor, and frame eye movements thanks to an infrared camera mounted on the device, capturing the image of the eye reflected on a

silver mirror placed in front of the eye itself. The software, running on a PC connected to the Natus ICS Impulse device, performs eye detection on real time images recorded by the camera and combines this data with information coming from the accelerometric sensor. In contrast, Synapsys VHIT device consists of an infrared remote-camera that frames the subject's face without the need for goggles, avoiding any contact between patient and device. The device lights up the subject's face, placed 90 cm from the camera, thanks to a built-in infrared illuminator. Synapsys VHIT software, running on a PC connected to the device, measures eyes and head velocities using software algorithms for eye tracking and head pose estimation, based on analysis of real time images recorded by the camera. Moreover, while Natus ICS Impulse can track and analyze the right eye only, due to the infrared camera permanently fixed on the right side of the goggle, the Inventis Synapsys VHIT can record and analyze both eyes during lateral head impulses.
Both Synapsys VHIT and Natus ICS Impulse devices enable to perform Video Head Impulse Tests on Lateral, Anterior and Posterior planes, allowing comprehensive assessment of all six semicircular canals. They also both provide the same clinical metrics, including VOR gain, head peak velocities, and quantitative data on detected covert saccades. Additionally, they display a range of informative graphs, such as an overall VOR Gain summary of the performed examination, time-based head and eye velocity traces for each maneuver, and a Gain vs. Head Peak Velocity graph.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The Synapsys VHIT device underwent a comprehensive series of tests for its Verification and Validation. These tests included verification of all VHIT software and system requirements within their intended operating environment. The testing covered various aspects, including functionality, performance, usability, interfaces, stability, safety and security, ensuring that the Synapsys VHIT device meets its defined software and system specifications.
The Synapsys VHIT device was further tested and validated according to the following standards:
• IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
• IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
• IEC 60601-1-6: App. Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
• IEC 62366-1: Medical devices - Application of usability engineering to medical devices
• IEC 62304: Medical device software – Software life cycle processes.
• IEC 82304-1: Health software – Part 1: General requirements for product safety
• IEC 62471: Photobiological safety of lamps and devices using lamps
• ISO 14971: Medical devices – Application of risk management to medical devices.
• ISO 15223-1: Graphical symbols used for the labeling of medical devices
• ISO 20417: Medical devices - Information to be supplied by the manufacturer
• ISO 17664-2: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-critical medical devices
• ANSI ASA S3.45: American National Standard Procedures for Testing Basic Vestibular Function
• IEC 81001-5-1: Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle
• IEC TR 60601-4-2: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
In addition to the tests performed for Verification and Validation of System and Software requirements of Synapsys VHIT device, a comparative analysis of VOR gain measurement has been conducted in Synapsys VHIT and ICS Impulse.
Each device has been used, according to the information reported in their User Manual, to perform a test both on pathological and non-pathological patients.
The primary emphasis of the analysis was to verify that the average VOR Gain computed by the two devices fell within a confidence interval of ±0.1. Secondary to this goal, we examined the trajectories to assess whether they exhibited similar patterns or behaviors.
The results of the comparative analysis demonstrate that the VOR gain differences fall within the predefined confidence interval of ±0.1. This provides evidence that the devices are equivalent for clinical practice, in both pathological and non-pathological subjects. Additionally, the consistency observed in the trajectories of head and eye movements during head impulse maneuvers further bolsters the case for their equivalence.
In conclusion, the bench and comparative testing results confirm the substantial equivalence (SE) of the Inventis Synapsys VHIT device with the predicate device Natus ICS Impulse.