



July 26, 2021

Metrovision
Jacques Charlier
CEO
4 rue des Platanes
Perenchies, Hauts de France 59840
France

Re: K211643
Trade/Device Name: Vision Monitor - MonpackONE
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked Response Photic Stimulator
Regulatory Class: Class II
Product Code: GWE, HLT
Dated: May 18, 2021
Received: May 27, 2021

Dear Jacques Charlier:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K211643

Device Name

Vision Monitor - MonPackONE

Indications for Use (Describe)

The Vision Monitor MonPackONE system is an electrodiagnostic device used to generate photic signals and to measure and display the electrical signals generated by the retina and the visual nervous system. It displays digitized electroretinogram (ERG), visual evoked potential (VEP) and sensory electro-oculogram (EOG) signals, power spectra and topographic maps. These functions are controlled and interpreted by trained medical professionals.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
K211643
for the Vision Monitor MonPackONE
Prepared July 22, 2021

Company name: METROVISION
4 rue des Platanes
59840 PERENCHIES
France
Telephone: + 33 3 20 17 19 50

Contact Person: Jacques CHARLIER, CEO
Email: charlier@metrovision.fr

Name of the device: VISION MONITOR MonPackONE

Classification name: 21 CFR 882.1890, Evoked response photic stimulator

Regulatory class: Class II

Product Code: GWE

Subsequent product code, based on other device functions in Class II : HLT

A. Legally Marketed Predicate Device

The Vision Monitor MonPackONE system is substantially equivalent to RETI-Port/SCAN systems manufactured by ROLAND CONSULT 510(k) number K023525.

They are all hardware and software products. The Vision Monitor MonPackONE system is substantially equivalent to the predicate device with regard to device features and specifications as well as intended use. All devices are visual evoked response test systems with similar operating requirements that are based on standard clinical procedures. Devices consist of hardware and software to provide photic stimulations and analysis of the evoked response data collected.

B. Device description

Photopic stimuli are presented to the patient on a LCD-screen at a various number of elements in separately stimulated fields. Various modes are available for preferential stimulation of different retinal mechanism and isolation of signal from different retinal layers. Data is recorded by up to 5 recording channels using conventional EEG electrodes (not provided with the device).

During the period of time that the system is acquiring data (1-20 minutes), there is a real time display of the raw and processed data presented to the user. Once the resulting individual waveforms are acquired, the signals are analyzed by software using algorithms for spatial filtering and artifact rejection. Data may be presented in a number of forms, including waves recorded at each of the points tested, color plots, or 3D topographical representation.

C. Intended Use/ Indications for Use

The Vision Monitor MonPackONE system is an electrodiagnostic device used to generate photic signals and to measure and display the electrical signals generated by the retina and the visual nervous system. It displays digitized electroretinogram (ERG), visual evoked potential (VEP) and sensory electro-oculogram (EOG) signals, power spectra and topographic maps. These functions are controlled and interpreted by trained medical professionals.

Substantial equivalence

Attribute	Submission device MonPackONE Metrovision	RETI-Port/SCAN Roland Consult
Intended use: Generate photic signals and measure and display the electrical response signals generated by the retina and the visual nervous system	YES	YES
Intended users: Ophthalmologists and trained medical technicians and professionals	YES	YES
Indications for use: Quantification of the electrophysiological response of the retina and visual cortex	YES	YES
Intended population: Patients with ophthalmic conditions	YES	YES
Intended use environment: Hospitals, clinics and physician offices	YES	YES
Physiological data collected: ERG and VEP waveforms	YES	YES
Compliance with recognized standards: ISO/EN 60601-1-2	YES	YES

Safety

The stimulator and the amplifier comply with ISO/EN 60601-1-2

The patient eye is exposed to visual light and near infra-red light with levels of exposure that have been measured and represents no risk to the patient.

Performance Data

The Vision Monitor MonPackONE was tested to the following standards:

- ISO 14971: 2012 Medical devices – Application of risk management to medical devices
- IEC 60601-1: 2012 - Medical devices General requirements for safety and essential performances
- IEC 60601-1-2: 2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 62366-1: 2015 Medical devices Application of usability engineering
- IEC 62304: 2015 Medical device. Software life cycle
- ANSI Z80.36-2016 Light hazard protection for ophthalmic instruments

The non-clinical testing completed for the Vision Monitor MonPackONE included these three major categories of testing:

Technical tests:

Internal hardware, firmware and Softwares component tests, packaging and labelling tests. Softwares verification and validation have been tested against their specifications and according to IEC 62304: 2015.

Functional tests:

The different functions needed to realize electroretinograms (ERG), visual evoked potentials (VEP) and sensory electro-oculograms (EOG) were tested according to the recommendations of the International Society of Clinical Electrophysiology of Vision (ISCEV).

Compatibility tests:

Compatibility of the equipment and software with the major types of electrodes was tested for the different exams performed by the equipment.

Conclusion

The VISION MONITOR MonPackONE and the RETI-Port/SCAN 21 have the same intended use and very similar indications, technological characteristics and principles of operation. Any technological differences between the VISION MONITOR MonPackONE and its predicate do not present any new issues of safety or effectiveness.

Bench testing has demonstrated that the VISION MONITOR MonPackONE is substantially equivalent to the predicate RETI-Port/SCAN 21.