November 21, 2022

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

Re: K212936
Trade/Device Name: Vision Monitor- MonCvONE
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked Response Photic Stimulator
Regulatory Class: Class II
Product Code: GWE, HLT
Dated: October 12, 2022
Received: October 17, 2022

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,

Elvin Y. Ng -S

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

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)*
K212936

Device Name
Vision Monitor - MonCvONE

Indications for Use *(Describe)*

The Vision Monitor MonCvONE system is a non-invasive medical device used to generate photic stimulations and to register the electrical responses generated by the retina and the visual nervous system in addition to psychophysical and pupillary responses. It displays digitized electroretinogram (ERG), visual evoked potential (VEP), sensory electro-oculogram (EOG), 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.

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510(k) SUMMARY
for the Vision Monitor MonCvONE
Prepared October 12th 2022

Company name: METROVISION
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France
Telephone: + 33 3 20 17 19 50

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

Name of the device: VISION MONITOR MonCvONE

Classification name: 21 CFR 882.1890, Evoked response photic stimulator

Regulatory class: Class II

Product Code: GWE
Secondary product code: HLT
Other functions (510(k) exempt): HPT, HLG, OUM

A. Legally Marketed Predicate Device

The Vision Monitor MonCvONE 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 MonCvONE 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 hemispherical cupola. Various modes are available for preferential stimulation of different visual functions. Electrophysiological data is recorded by up to 5 recording channels using conventional EEG electrodes (not provided with the device). Psychophysical responses are recorded with a press button and pupillometry responses recorded with an eye tracker.
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 operator. Once the resulting individual responses 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 MonCvONE system is a non-invasive medical device used to generate photic stimulations and to register the responses including electrical responses generated by the retina and the visual nervous system in addition to psychophysical and pupillary responses. It displays digitized electroretinogram (ERG), visual evoked potential (VEP), sensory electro-oculogram (EOG), light and dark adapted perimetry thresholds, dark adaptometry, full field stimulus threshold (FST), photo aversion thresholds (PAT), pupillometry as curves, power spectra and topographic maps. These functions are controlled and interpreted by trained medical professionals.

Substantial equivalence

Attribute	Submission device MonCvONE 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

The Indications for Use statement for the MonCvONE device is not identical to the predicate device. The MonCvONE includes additional means of response including psychophysical responses and pupillometry that provide additional information contributing to the interpretation of responses from patients with ophthalmic conditions. However, the differences do not alter the intended diagnosis use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

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 MonCvONE 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 MonCvONE included these three major categories of testing:
Technical tests which include: 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
012_Vision electrophysiology software test report
013_Sensory EOG software test report

Functional tests:
014_Flash and pattern ERG and VEP functional tests.pdf
015_Sensory EOG functional tests.pdf

Compatibility tests with PC and accessories used:
016_PC compatibility
017_Accessories compatibility

Other functions
This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

Conclusion

The VISION MONITOR MonCvONE 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 MonCvONE and its predicate do not present any new issues of safety or effectiveness.
Bench testing has demonstrated that the VISION MONITOR MonCvONE is as safe, as effective and performs as well or better than the legally marketed device.