November 22, 2022

Diagnosys LLC
Jeffrey Farmer
CEO
55 Technology Drive, Suite 100
Lowell, Massachusetts 01851

Re: K221471
Trade/Device Name: E3 and Profile
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked Response Photic Stimulator
Regulatory Class: Class II
Product Code: GWE, HLT
Dated: October 27, 2022
Received: October 28, 2022

Dear Jeffrey Farmer:

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)*
K221471

Device Name
E3 and Profile

Indications for Use *(Describe)*
The E3 and Profile 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, for use with patients who are experiencing visual system abnormalities.

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 E3 and Profile
PER 21 CFR 807.92

Date prepared: October 24, 2022

Company name: Diagnosys LLC
55 Technology Drive, Suite 100
Lowell, MA 01851
USA
Telephone: 1-978-458-1600
Fax: 1-978-458-1755

Contact Person: Jeffrey Farmer, CEO
Email: jeff@diagnosysllc.com

Name of the device: E3, Profile

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 E3 and Profile (also known as the Espion Ophthalmic Electrophysiology System) is substantially equivalent to the Vision Monitor MonPackONE system manufactured by MetroVision 510(k) number K211643. They are both hardware and software products. The E3 and Profile is substantially equivalent to the predicate devices 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 that is collected.

B. Device Description

Photopic stimuli are presented to the patient using LEDs or a monitor, using 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,

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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 E3 and Profile 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, for use with patients who are experiencing visual system abnormalities.

Substantial equivalence

Attribute	Submission device E3, Profile Diagnosys LLC	MonPackONE Metrovision
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, VEP, EOG waveforms	YES	YES
Compliance with recognized standards: ISO/EN 60601-1-2	YES	YES

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Materials	Aluminum, molded parts, machined parts, PCBAs, PC, LCD monitor, LED and LCD light sources	Aluminum, molded parts, machined parts, PCBAs, PC, LCD monitor, LED and LCD light sources
Design	LCD display, Ganzfeld stimulator, amplifier, built in camera, desktop and electric stand option, PC	LCD display, Ganzfeld stimulator, amplifier, built in camera, desktop and electric stand option, PC
Energy Source	LCD monitor with LED backlight; LEDs	LCD monitor with LED backlight; LEDs
Other design features	Protocols to run all ISCEV clinical protocols; movable head and chin rests	Protocols to run all ISCEV clinical protocols; movable head and chin rests

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 E3 and Profile was tested and/or assessed to the following standards:
1. IEC 60601-1:2012. Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.
2. ISO 14971: 2012 Medical devices – Application of risk management to medical devices.
3. IEC 60601-1-2:2014. Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.
4. IEC 62366-1: 2015. Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices.
5. IEC 60601-1-6:2010, AMD1:2013. Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability.
6. IEC 60601-2-26:2012. Medical Electrical Equipment - Part 2-26: Particular Requirements For The Basic Safety And Essential Performance Of Electroencephalographs.
7. IEC 62304:2015. Medical Device Software - Software Life Cycle Processes.
8. ANSI Z80.36-2021 Light hazard protection for ophthalmic instruments.
9. ISO 10993-1. Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
10. ISO 10993-5. Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
11. ISO 10993-10. Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

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12. ISO 10993-23. Biological evaluation of medical devices - Part 23: Tests for irritation.

The non-clinical testing completed for the E3 and Profile included these three major categories of testing:

Technical tests:
Internal hardware, firmware and software component tests, packaging and labeling tests. Software verification and validation have been tested against their specifications and according to IEC 62304: 2015.

Functional tests:
The different functions needed to measure 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 E3 and Profile and the Vision Monitor MonPackONE system have the same intended use and indications, technological characteristics and principles of operation. Any technological differences between the E3 and Profile and its predicate does not present any new issues of safety or effectiveness. Testing has demonstrated that the E3 and Profile is substantially equivalent to the predicate device.

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