December 7, 2023

RetMap, Inc.
Shresta Patangay
Chief of Staff
832 W Superior St, Suite 202
Chicago, Illinois 60642

Re: K232273
Trade/Device Name: RM Electrode (RMH 23-01)
Regulation Number: 21 CFR 886.1220
Regulation Name: Corneal electrode
Regulatory Class: Class II
Product Code: HLZ
Dated: November 3, 2023
Received: November 3, 2023

Dear Shresta Patangay:

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.

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,

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.

Submission Number *(if known)*

K232273

Device Name

RM Electrode (RMH 23-01)

Indications for Use *(Describe)*

The RM Electrode® is a contact lens electrode intended to be applied on the cornea and to be used for the measurement and recording of electroretinography (ERG) signals, to support the diagnosis of retinal dysfunctions. It is indicated for use in patients aged 12 years and above undergoing diagnostic full-field electroretinogram (ERG) recording procedures.

The RM Electrode® is a single use, disposable device.

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

K232273

Premarket Notification (510(k)) Number

Submitter's Name	RetMap, Inc. 832 W Superior St., Suite 202 Chicago, IL 60642 Telephone: (312) 224-8938
Contact Person	Shresta Patangay, PhD Chief of Staff RetMap, Inc. 832 W Superior St., Suite 202 Chicago, IL 60642
Date Prepared	July 28, 2023
Device Trade Name	RM Electrode
Device Common Name	Corneal or ERG Electrode
Classification Name	Corneal Electrode
Product Code	HLZ
Device Classification	Class II
Panel	Ophthalmology
Regulatory Classification	21 CFR 886.1220
Type of 510(k) Submission	Traditional
Legally Marketed Predicate Device	ERG Jet Electrode (K813399)

Description

The RM Electrode® is a contact lens-type corneal electrode for use in electroretinography (ERG) procedures. Like other corneal electrodes classified under 21 CFR 886.1220 and cleared under product code HLZ, the RM Electrode is used for the measurement and recording of ERG signals, to support the diagnosis of retinal dysfunctions. It has four components, including (1) the contact lens (substrate), which supports the conductive element (electrode ring) and allows light from the stimulus source to enter the eye; (2) the electrode ring, which is the conductive element of the device; (3) the lead wire, which is connected to the electrode ring extension and terminates in an industry standard 1.5mm female "touchproof" connector that connects to a commercially available ERG recording system (not part of the subject device); and (4) heat shrink tubing which covers the electrode ring extension and junction with the lead wire. The device materials were demonstrated to be biocompatible.

The RM Electrode® is not a powered device. As with the predicate device (ERG Jet Electrode), it is a passive sensor for recording bioelectric signals from the surface of the eye and transmitting them to an ERG recording system. From an electrical perspective, the device is a single conductor that connects the eye surface to a data recorder.

Indications for Use

The RM Electrode® is a contact lens electrode intended to be applied on the cornea and to be used for the measurement and recording of electroretinography (ERG) signals, to support the diagnosis of retinal dysfunctions. It is indicated for use in patients aged 12 years and above undergoing diagnostic full-field electroretinogram (ERG) recording procedures.

The RM Electrode® is a single use, disposable device.

Predicate Device

The RM Electrode® is substantially equivalent to the ERG Jet Electrode cleared under K813399. Both devices are electrodes intended to be applied on the cornea for the measurement and recording of ERG signals, to support the diagnosis of retinal dysfunctions. Both the subject and predicate devices have the same intended use and similar technological characteristics, but the RM Electrode includes a softer eye contact material and design features that help prevent the wearer from blinking during the ERG test, improve positional stability, and keep the area of the pupil clear of obstructions.

Please refer to the Substantial Equivalence Summary Comparison Table below for a summary of the similarities and differences between the subject and predicate devices.

Description of Operation

As part of an ERG procedure, the device is filled with a lubricating ophthalmic solution and placed on the eye. The lead wire is gently draped over the ipsilateral ear, secured with tape if needed, and the connector is plugged into a compatible ERG recording system. The device can be used for any full-field ERG protocol to record bioelectric signals from the surface of the eye and transmit them to the ERG data recording system. After the ERG test procedure, the device is removed from the patient's eye.

Technological Characteristics Summary

The RM Electrode is substantially equivalent to the ERG Jet Electrode (K813399) with respect to intended use, design, principle of operation, technological characteristics and performance. Both devices include similar components, including a contact lens (eye contact) portion, electrode, and lead wire with connector. The RM Electrode includes a softer eye contact material and design features that help prevent the wearer from blinking during the ERG test, improve positional stability, and keep the area of the pupil clear of obstructions. These differences do not raise new questions of safety or effectiveness.

Substantial Equivalence Summary Comparison Table

Features	**RM Electrode (Subject Device)**	**ERG Jet Electrode Predicate Device K813399**	**Comparison**
Intended Use	Corneal (contact lens) electrode to transmit the retinal electrical signal in diagnostic ERG procedures	Corneal (contact lens) electrode to transmit the retinal electrical signal in diagnostic ERG procedures	Identical
Product Code	HLZ	HLZ	Identical
Indications for Use	The RM Electrode® is a contact lens electrode intended to be applied on the cornea and to be used for the measurement and recording of	The ERG-Jet is a contact lens electrode intended to be applied on the cornea and to be used for the measurement and recording of	Equivalent. While the predicate device is intended for use in both full-field flash and multi-focal ERG procedures, the subject device is

	electroretinography (ERG) signals, to support the diagnosis of retinal dysfunctions. It is indicated for use in patients aged 12 years and above undergoing diagnostic full-field electroretinogram (ERG) recording procedures. The RM Electrode® is a single use, disposable device.	electroretinography (ERG) signals, to support the diagnosis of retinal dysfunctions. The ERG-Jet is not intended for multiple use. If re-used, an infection of the cornea can occur, and the measuring results are no longer guaranteed.	currently intended only for use in full-field flash ERG procedures. Full-field flash protocols represent the majority (approximately 80%) of the ERG procedures conducted in the United States, therefore this difference is not critical to the intended use of the device and does not affect the safety or effectiveness of the device when used as labeled. The device labeling clearly identifies the intended use for full-field flash procedures only.
Target Population	Patients aged 12 years and above undergoing ERG recording procedures	Patient population not specified	Both devices are used in patients undergoing ERG procedures
Types of ERG Procedures	Full-field flash ERG protocols	Either full-field or multifocal ERG protocols	The RM Electrode is not intended for ERG protocols that use patterned visual stimuli, such as the multi-focal ERG (mfERG). Full-field flash protocols represent approximately 80% of ERG procedures that

			are conducted in the US thus this difference is not critical to the intended use of the device and does not affect the safety or effectiveness of the device when used as labeled.
Wear Duration	Typically 20 minutes. < 1 hour	Typically 20 minutes. < 1 hour	Identical
Intended Users	Ophthalmologists, optometrists, trained medical technicians and professionals and vision science researchers	Ophthalmologists and optometrists practicing in ophthalmic hospitals, clinics and medical settings	Equivalent intended users
Environment of Use	Hospitals, clinics, physician offices, research labs	Ophthalmic hospitals, clinics and medical settings	Equivalent medical setting use environments
Components	Contact lens, electrode ring, lead wire with 1.5mm touchproof connector that connects to ERG data recorder	Contact lens, electrode, lead wire with 1.5mm touchproof connector that connects to ERG data recorder	Equivalent components
Materials	Biocompatible materials	Biocompatible materials	Equivalent materials
Compatible ERG Recorders	ERG recording system accepting 1.5mm touchproof connector that complies with all applicable device safety standards, such as IEC 60601-1	ERG recording system accepting 1.5mm touchproof connector that complies with all applicable device safety standards, such as IEC 60601-1	Identical

Performance Testing

As described below, a comprehensive battery of biocompatibility, bench, and clinical studies was submitted to confirm product conformance with device requirements. Performance data demonstrated biocompatibility, absence of ocular irritation in both animals and humans, and substantially equivalent performance to the predicate device in terms of ERG signal quality, lead

wire integrity and electrical impedance. The biocompatibility, bench, shelf life, and clinical studies summarized below concluded that the device is as safe, as effective, and performs as well or better than the legally marketed predicate device.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993. Testing was successfully completed for cytotoxicity, sensitization and ocular irritation. In addition, human ocular irritation was completed following 60 minutes of wear time (approximately 3 times the typical 20-minute wear duration) in 10 subjects with both the subject and predicate devices. Bulbar redness, limbal redness, tarsal redness, and corneal abrasion associated with wear of the subject device were found to be equivalent to, or less than, that associated with wear of the predicate device.

Bench Testing

The subject and predicate device were tested under tensile load to determine the failure load for the lead wire-electrode ring junction. The subject device failure load was significantly higher (better) than that for the predicate device. In addition, all samples of the subject device met the prospectively defined acceptance criteria for the minimum failure load.

The subject and predicate device were also evaluated for electrical impedance measured at three frequencies within the passband of the ERG signal. At all frequencies, the electrical impedance of the subject device was equivalent to, or less than (better) that of the predicate device.

Shelf Life Testing

The device and its packaging successfully completed evaluations after accelerated aging to support the labeled shelf life. Integrity of the sterile packaging was confirmed before and after accelerated aging through seal strength and bubble leak testing. Device properties were confirmed before and after accelerated aging through evaluation of material hardness of the eye contact portion of the device using a calibrated durometer and through evaluation of the electrical impedance of the device measured at three frequencies within the passband of the ERG signal. All samples met the acceptance criteria demonstrating no significant changes over the labeled shelf life.

Clinical Testing

Clinical performance testing was compared using the subject and predicate devices in 15 subjects at two sites who sequentially wore both devices in the same eye in a randomized order. Subjects

were healthy with no history of retinal disease or corneal surgery. Full-field flash (ISCEV LA 3.0 stimulus) and 30 Hz flicker ERG protocols were followed. Amplitudes (a-wave, b-wave and flicker) and signal to noise ratios were substantially equivalent for both devices. There were no adverse events or complications related to the subject device.

In addition, as noted in the Biocompatibility section above, human ocular irritation was completed following 60 minutes of wear time (approximately 3 times the typical wear duration) in 10 subjects with both the subject and predicate devices. Subjects were normally sighted aged 18 years and above. Bulbar redness, limbal redness, tarsal redness, and corneal abrasion associated with wear of the subject device were found to be equivalent to, or less than, that associated with wear of the predicate device. There were no adverse events or complications related to the study device.

Conclusions

The nonclinical and clinical studies demonstrated the subject device is (1) biocompatible (lack of cytotoxicity, ocular irritation in animals or humans, or sensitization); (2) maintains device (material hardness of the eye contact portion and electrical impedance) and package integrity (seal strength and bubble leak) after a 1-year shelf life; (3) has substantially equivalent or better performance with respect to lead wire integrity and electrical impedance compared to the predicate device; and (4) can be used successfully in full-field ERG protocols with comparable results (amplitudes and signal to noise ratios) as the predicate device. These results demonstrate that the RM Electrode is as safe, as effective, and performs as well or better than the legally marketed device identified above.

Summary

In summary, the RM Electrode is substantially equivalent to the predicate ERG Jet Electrode with respect to intended use, technological characteristics and performance. The biocompatibility, bench, shelf life, and clinical studies concluded that the device is as safe, as effective, and performs as well or better than the legally marketed predicate device.