April 1, 2026

Retmap, Inc.
Shresta Patangay
Chief Operating Officer
832 W Superior St., Suite 302
Chicago, Illinois 60642

Re: K253586
Trade/Device Name: RM Electrode (RMH 25-01)
Regulation Number: 21 CFR 886.1220
Regulation Name: Corneal electrode
Regulatory Class: Class II
Product Code: HLZ
Dated: February 25, 2026
Received: February 25, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Alexander Beylin -S Date: 2026.04.01 12:06:28 -04'00'

for CAPT Bradley Cunningham, MSE, RAC
Acting 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253586

Please provide the device trade name(s).

RM Electrode (RMH 25-01)

Please provide your Indications for Use below.

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 and multi-focal electroretinogram (ERG) recording procedures.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
K253586
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 Operating Officer RetMap, Inc. 832 W Superior St., Suite 202 Chicago, IL 60642
Date Prepared	February 25, 2026
Device Trade Name	RM Electrode Model Number: RMH 25-01
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 Devices	RM Electrode (K232273) (primary predicate device) ERG Jet Electrode (K813399) (secondary predicate device)

Device 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. Like the original version of the device cleared under K232273, the subject device (RM Electrode (RMH 25-01)) 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 RM Electrode® is not a powered device. As with the primary predicate device (RM Electrode®, K232273), the secondary predicate device (ERG Jet Electrode, K813399), and other commonly used ERG electrodes, the subject RM Electrode® (RMH 25-01) 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 and multi-focal electroretinogram (ERG) recording procedures.

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

Primary Predicate Device

The RM Electrode® (RMH 25-01) is substantially equivalent to the RM Electrode® cleared under K232273 (primary predicate device). 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 primary predicate devices have the same intended use and nearly identical technological characteristics, but the subject RM Electrode® (RMH 25-01) has optical characteristics that are suitable for use in multi-focal ERG testing (as well as the previously cleared use of the predicate device in full-field ERG testing), and a shape feature

intended to improve user workflow in distinguishing the eye-contact side from the distal (non-eye contact) side under the dim lighting conditions often present when preparing ERG electrodes prior to installation.

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 or multi-focal 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 subject RM Electrode (RMH 25-01) is substantially equivalent to the currently marketed RM Electrode (K232273) and the secondary predicate device (ERG Jet Electrode, K813399) with respect to intended use, design, principle of operation, technological characteristics and performance. Other than the shape feature included in the subject device described above), the overall shape and design are identical to the primary predicate device. Both the subject and primary predicate RM Electrodes include a soft contact lens (eye contact) portion, electrode, and lead wire with connector. Like the secondary predicate device, the subject device (RM Electrode (RMH 25-01)) can be used for both multi-focal and full-field ERG procedures. These differences do not raise new questions of safety or effectiveness.

Substantial Equivalence Summary Comparison Table

Features	RM Electrode (RMH 25-01) (Subject Device)	RM Electrode Primary Predicate Device (K232273)	ERG Jet Electrode Secondary 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	Corneal (contact lens) electrode to transmit the retinal electrical signal in diagnostic ERG procedures	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 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 and multi-focal electroretinogram (ERG) recording procedures.	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 ERG-Jet supports the diagnosis of retinal dysfunctions, such as the assessment of retinal function impairment that can occur with retinal disease and/or neurological conditions. 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 electroretinography (ERG) signals, to support the diagnosis of retinal dysfunctions. It can be	Equivalent. Both the subject RM Electrode (RMH 25-01) and the primary predicate device are indicated for full-field ERG testing in patients aged 12 years and above. Both the subject device and the secondary predicate device are intended for use in full-field and multi-focal ERG procedures.

Features	RM Electrode (RMH 25-01) (Subject Device)	RM Electrode Primary Predicate Device (K232273)	ERG Jet Electrode Secondary Predicate Device (K813399)	Comparison
	The RM Electrode® is a single use, disposable device.	The RM Electrode® is a single use, disposable device.	used to perform either full-field or multifocal ERG assessment.	The subject and both predicate devices are single-use, disposable devices.
Product Code	HLZ	HLZ	HLZ	Identical
Target Population	Patients aged 12 years and above undergoing ERG recording procedures	Patients aged 12 years and above undergoing ERG recording procedures.	The target patients are adults and adolescents that require an ERG testing.	Identical. The subject and both predicate devices are used in adolescent and adult patients undergoing ERG procedures.
Types of ERG Procedures	Full-field and multi-focal ERG protocols	Full-field ERG protocols	Full-field and multi-focal ERG protocols.	The currently marketed RM Electrode (primary predicate device) is intended for full-field ERG protocols only. The subject RM Electrode (RMH 25-01) and secondary predicate are both intended for use in multi-focal and full-field ERG procedures.

Features	RM Electrode (RMH 25-01) (Subject Device)	RM Electrode Primary Predicate Device (K232273)	ERG Jet Electrode Secondary Predicate Device (K813399)	Comparison
Wear Duration	Typically 20 minutes; range 5-60 minutes. The RM Electrode® (RMH 25-01) is not indicated to be used for more than one hour.	Typically 20 minutes; range 5-60 minutes. The RM Electrode® is not indicated to be used for more than one hour.	Typically 20 minutes; range 5-60 minutes The ERG-Jet is not indicated to be used more than one hour.	Identical
Intended Users	Ophthalmologists, optometrists, trained medical technicians and professionals and vision science researchers	Ophthalmologists, optometrists, trained medical technicians and professionals and vision science researchers	The user(s) profile are ophthalmologists and optometrists (under the supervision of an ophthalmologist) practicing in ophthalmic hospitals, clinics, and medical settings.	Equivalent.
Environment of Use	Hospitals, clinics, physician offices, research labs	Hospitals, clinics, physician offices, research labs	Ophthalmic hospitals, clinics, and medical settings.	Equivalent.
Types of Device Components	Contact lens, electrode ring, lead wire with 1.5mm touchproof connector that connects to ERG data recorder.	Contact lens, electrode ring, lead wire with 1.5mm touchproof connector that connects to ERG data recorder.	Contact lens that is highly transparent in the visible spectrum. Gold film electrode ring	The subject and primary predicate device have identical types of components. The subject device additionally includes a shape feature to

Features	RM Electrode (RMH 25-01) (Subject Device)	RM Electrode Primary Predicate Device (K232273)	ERG Jet Electrode Secondary Predicate Device (K813399)	Comparison
	Subject device additionally has a shape feature intended to improve user workflow in distinguishing the eye-contact side from the distal (non-eye contact) side under the dim lighting conditions often present when preparing ERG electrodes prior to installation		Lead wire approximately 1 meter in length with 1.5mm touchproof connector that connects to ERG data recorder.	improve user workflow by making the eye-contact and distal sides of the device easier to distinguish during device preparation prior to installation. The subject and secondary predicate devices have equivalent types of components.
Materials	Biocompatible materials	Biocompatible materials	Biocompatible materials	Equivalent materials The material of the subject and primary predicate RM Electrodes that contacts the eye is a soft Class VI silicone rubber, which minimizes the risk of corneal abrasion. The materials of the secondary predicate

Features	RM Electrode (RMH 25-01) (Subject Device)	RM Electrode Primary Predicate Device (K232273)	ERG Jet Electrode Secondary Predicate Device (K813399)	Comparison
				device that contact the eye are hard acrylic and the metal electrode ring. In the subject and primary predicate RM Electrodes, the electrode ring is recessed within the contact lens portion so that it makes no direct contact with the eye.
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	All ERG recording systems accepting 1.5mm touchproof connectors that comply with all applicable device safety standards, such as IEC 60601-1	Identical

Performance Testing

As described below, a comprehensive battery of ocular irritation, bench, and clinical studies was submitted to confirm product conformance with device requirements and substantial equivalence to the predicate. Performance data demonstrated the absence of ocular irritation in humans and rabbits and substantially equivalent performance to the predicate device(s) (as applicable) in terms of ERG signal quality, lead wire integrity, electrical impedance, and optical characteristics.

Clinical performance testing comparing performance of the subject device in multi-focal ERG (mfERG) procedures to the secondary predicate device (ERG Jet Electrode cleared under K813399), which is another legally marketed ERG electrode indicated for use in mfERG procedures, demonstrated equivalence, as did clinical testing comparing performance of the subject and predicate RM Electrodes® in full-field ERG procedures.

The ocular irritation, 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.

Ocular Irritation Testing

Ocular irritation in human participants was evaluated following 60 minutes of wear time (approximately 3 times the typical 20-minute wear duration) in 10 subjects with both the subject and primary 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.

Additionally, ocular irritation testing was successfully completed in rabbits per ISO 10993-23 Biological evaluation of medical devices – Part 23: Tests for irritation. The test articles were modified RM Electrodes (subject device, model RMH 25-01) in their final, finished, sterilized form. Testing was performed by an independent third-party testing laboratory. All measures of irritation of the cornea, iris and conjunctiva, in all six rabbits, and at all four time points (1, 24, 48 and 72 hours after exposure) were identical to the control eyes.

Bench Testing

The subject and primary predicate devices were tested under tensile load to determine the failure load for the lead wire-electrode ring junction. The subject device failure load was substantially equivalent to 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 primary predicate devices 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 substantially equivalent to the predicate device.

Additionally, relevant device optical properties (local blur and distortion) were compared between the subject, primary, and secondary predicate devices to demonstrate equivalence and appropriateness for the subject device intended use.

Shelf-Life Testing

The subject 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 **1)** evaluation of material hardness of the eye contact portion of the device using a calibrated durometer, **2)** evaluation of the electrical impedance of the device measured at three frequencies within the passband of the ERG signal and **3)** evaluation of the failure load of the lead wire-electrode junction. All samples met the acceptance criteria demonstrating no significant changes over the labeled shelf life. All samples tested met the prospectively defined acceptance criteria for impedance, material hardness and failure load.

Clinical Testing

Clinical performance testing was compared using the subject and primary predicate devices in 5 subjects 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.

Additional clinical performance testing in 10 subjects compared the subject device and the secondary predicate device (ERG Jet Electrode – K813399) for performance in multi-focal ERG (mfERG) testing. A 61-hexagon stimulus conforming to ISCEV standards for clinical electroretinography was used. Subjects wore the subject and secondary predicate devices in the same eye in a randomized order. Amplitudes of response peaks were substantially equivalent for both devices, thus demonstrating suitability of the proposed use of the device in mfERG procedures. As noted above, the secondary predicate (ERG Jet Electrode) was used for this comparative testing since it is indicated for use in mfERG testing while the primary predicate RM Electrode® is indicated for use in only full-field ERG procedures. There were no adverse events or complications related to the subject device.

In addition, as noted in the Ocular Irritation Testing 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 primary 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 primary predicate device. There were no adverse events or complications related to the study device.

Summary

In summary, the RM Electrode (RMH 25-01) is substantially equivalent to the primary predicate RM Electrode (currently marketed, K232273) and the secondary predicate (ERG Jet Electrode, K813399) with respect to intended use, technological characteristics and performance.