December 27, 2022

Lutronic Vision, Inc.
℅ Dulciana Chan
Principal Consultant
Rqm+
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

Re: K220974
Trade/Device Name: R:gen
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: November 23, 2022
Received: November 25, 2022

Dear Dulciana Chan:

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,

Alexander Beylin -S

Date: 2022.12.27 17:58:40 -05'00'

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

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)*
K220974

Device Name
R:GEN

Indications for Use *(Describe)*
The R:GEN is indicated for use by an ophthalmic physician to produce a wound to the Retinal Pigmented Epithelium (RPE) of the retina of the eye, via focal laser treatment, in the treatment of Clinically Significant Macular Edema (CSME).

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
K220974

DATE PREPARED
December 22, 2022

510(k) OWNER
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DEVICE INFORMATION
Proprietary Name/Trade Name: R:GEN
Common Name: Laser, Ophthalmic
Regulation Number: 21 CFR § 886.4390
Class: II
Product Code: HQF
Premarket Review: OPEQ/OHT1/DHT1A/Retinal and Diagnostic Devices
Review Panel: Ophthalmic

PREDICATE DEVICE IDENTIFICATION
The R:GEN is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K153769	R:GEN Laser System	✓

Lutronic submits the following information to demonstrate that the R:GEN has similar technology to the following legally marketed reference devices:

510(k) Number	*Reference Device Name / Manufacturer*	*Reference Device*
K122202	Ellex 2RT /Ellex Medical	✓
K121475	TxCell Scanning Laser Deliver System /IRIDEX Corporation	✓
K123542	Pascal Synthesis Ophthalmic Laser/ IRIDEX Corporation	✓

DEVICE DESCRIPTION

The R:GEN is a surgical laser system for use by ophthalmic physicians for performing focal laser treatment, also referred to as selective retinal therapy for the treatment of various retinal diseases by wounding Retinal Pigmented Epithelium (RPE) cells. It is the product of continual technological evolution of the R:GEN technology described in the predicate device (K153769). It consists of the following main components: Main Body, LCD Monitor, Slit Lamp Set, Footswitch, and Real Time Feedback (RTF) Contact Lens which consists of the RTF Body (Real Time Feedback Body) and RTF Sensor (Real Time Feedback Sensor). The Main Body allows the proper operation of the entire system. It contains the laser and is attached to the Footswitch and optical fiber. The laser is a Q-switched Nd:YLF (Neodymium-doped Yttrium Lithium Fluoride) laser with an emission wavelength of 527 nm (produced by second-harmonic generation). The integrated software provides all the functions which are necessary to use the device. The Slit Lamp Set contains the laser delivery system. The laser beam emitted through the Slip Lamp Set is transmitted through the RTF Contact Lens (first through the RTF body and then through the RTF Sensor), and finally irradiated to the patient's retina.

INDICATIONS FOR USE

The R:GEN is indicated for use by an ophthalmic physician to produce a wound to the Retinal Pigmented Epithelium (RPE) of the retina of the eye, via focal laser treatment, in the treatment of Clinically Significant Macular Edema (CSME).

INTENDED USE

The subject device has the same intended use as the predicate device which is to produce a wound to the Retinal Pigmented Epithelium (RPE) of the retina of the eye.

SUBSTANIAL EQUIVALENCE

	Subject Device	***Predicate Device***	***Reference Device***	***Reference Device***	***Reference Device***
	Lutronic Vision Inc. R:GEN K220974	Lutronic Corporation R:GEN Laser System K153769	Ellex Medical Ellex 2RT K122202	IRIDEX Corporation TxCell Scanning Laser Delivery System K121475	IRIDEX Corporation Pascal Synthesis Ophthalmic Laser K123542
Intended Use	To produce a wound to the Retinal Pigmented Epithelium (RPE) of the retina of the eye	To produce a wound to the Retinal Pigmented Epithelium (RPE) of the retina of the eye	To produce a wound to the Retinal Pigmented Epithelium (RPE) of the retina of the eye	To deliver laser energy to various ocular targets	To deliver laser energy to various ocular targets
Indications for Use	The R:GEN is indicated for use by an ophthalmic physician to produce a wound to the Retinal Pigmented Epithelium (RPE) of the retina of the eye, via focal laser treatment, in the treatment of Clinically Significant Macular Edema (CSME).	The R:GEN Laser System is indicated for use by an ophthalmic physician to produce a wound to the Retinal Pigmented Epithelium (RPE) of the retina of the eye, via focal laser treatment, in the treatment of Clinically Significant Macular Edema (CSME)	The 2RT (LR1532) is indicated for use by a trained ophthalmic physician to produce a wound to the Retinal Pigmented Epithelium (RPE) of the retina of the eye, via focal laser treatment, in the treatment of Clinically Significant Macular Edema (CSME)	When the TxCell Scanning Laser Delivery System is connected to the IQ 532 (532 nm), the IQ 577 (577 nm) or the IQ 810 (810 nm) Laser Console, from the IRIDEX Family of IQ Laser Systems and used to deliver laser energy in CW-Pulse, MicroPulse or LongPulse mode, it is intended to be used by a trained ophthalmologist for the treatment of ocular pathology of both the anterior and posterior segments of the eye. 532 nm Indicated for retinal hotocoagulation, laser	The PASCAL® Synthesis Ophthalmic Scanning Laser System is intended for use in the treatment of ocular pathology in both the posterior and anterior segments. Intended for use in the posterior segment to perform retinal photocoagulation, panretinal photocoagulation. focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including: (532 nm) • proliferative and non-proliferative diabetic retinopathy • macular edema

				trabeculoplasty, iridotomy, iridoplasty including: Retinal photocoagulation (RPC) for the treatment of: Diabetic retinopathy, including: Nonproliferative retinopathy Macular edema Proliferative retinopathy Retinal tears and detachments Lattice degeneration Age-related macular degeneration (AMD) with choroidal neovascularization (CNV) Sub-retinal (choroidal) neovascularization Central and branch retinal vein occlusion Laser trabeculoplasty for the treatment of: Primary open angle glaucoma Laser iridotomy, iridoplasty for the treatment of: Angle closure glaucoma	• choroidal neovascularization associated with wet age-related macular degeneration • age-related macular degeneration • lattice degeneration • retinal tears and detachments (577nm) • proliferative and non-proliferative diabetic retinopathy • macular edema • choroidal neovascularization associated with wet age-related macular degeneration • age-related macular degeneration • lattice degeneration • retinal tears and detachments Intended for use in the treatment of ocular pathology in the anterior segment including: (532 nm and 577nm) • iridotomy trabeculoplasty
Patient Population	Adult	Adult	Adult	Adult	Adult
Product Code /	HQF/ 21 CFR 886.4390	HQF/ 21 CFR 886.4390	HQF/ 21 CFR 886.4390	GEX/ 21 CFR 878.4810	HQF/ 21 CFR 886.4390

Regulation Number					
Regulation Description	Ophthalmic Laser	Ophthalmic Laser	Ophthalmic Laser	Laser surgical instrument for use in general and plastic surgery and in dermatology	Ophthalmic Laser
Laser Type	Q-switched Nd:YLF Laser	Q-switched Nd:YLF Laser	Q-switched Nd:YAG Laser, frequency doubled	Frequency doubled solid-state	Pumped semiconductor (OPSL); solid-state
Laser Wavelength	527 nm (green)	527 nm (green)	532 nm	532 nm, 577 nm, 810 nm	532 nm or 577 nm
Laser Energy	0.03 mJ to 0.35 mJ	0.03 mJ to 0.4 mJ	Minimum: 0.1 mJ Maximum: 0.6 mJ 0.10-0.30 in 0.02 steps 0.30-0.60 in 0.05 steps	2W power	0.3mW-2000 mW power
Pulse Duration	1.7 µs	1.7 µs	0.003 µs No less than 500 ms for 20 continuous shots	Variable (≤100ms)	5-1000 ms
Aiming Beam	635 nm	635 nm	635 nm	635 nm	635 nm
Type of Delivery System	Slit lamp adapter with optical fiber connected to a separate laser source	Slit lamp adapter with optical fiber connected to a separate laser source	Slit lamp adapter with optical fiber connected to a separate laser source	Slit lamp adapter with optical fiber connected to a separate laser source	Slit lamp adapter with optical fiber connected to a separate laser source
Single Spot Size	200 µm	200 µm	400 µm	50-500 µm	50, 100, 200, 400 µm
Multi-spot Deliver Modes	Yes Square Pattern (2x2, 3x3, or 4x4) Circle Pattern (radius 500-2000 µm)	No	No	Yes Multi-spot patterns (100-500 µm spot sizes) Radius Grid (2x2, 3x3, 4x4, 5x5, 6x6,7x7)	Yes Multi-spot patterns (40-400 µm spot sizes) Array (1x1 to 5x5 grid) Triple Arc Wedge (3-sideded 3x3x3 to 6x6x6 segment)

	2 x 2 Combo Pattern			Rotation Arc Triple Arc Circle	Triple Ring Arc Line (1-10 spots in a line) Hexagon (6-sided array) Octant (up to 4 rings divided into 8 radial segments) Enhanced Octant (multiple rings from 500-3000 µm radius) Circle (1-3 rings in full or partial circle)
Screen	Touch LCD Module	Touch LCD Module	Tablet	Unknown	Touchscreen LCD Module
Emission Control	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch
Laser Contact Lens	RTF Contact Lens provided	Laser Contact Lens not provided	Laser Contact Lens not provided	Laser Contact Lens not provided	Laser Contact Lens not provided
Electrical Rating	AC 100-240V, 50/60 Hz, Power consumption 300VA	AC 100-240V, 50/60 Hz, Power consumption 300VA	100–240 VAC, 50/60 Hz	100–240 VAC, 50/60 Hz	100 – 230 VAC, 50/60 Hz

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The R:GEN that is the subject of this 510(k) employs the same mechanism of action as the predicate device and achieves its intended use with very similar technological characteristics when compared with the legally marketed predicate and reference devices. Differences in technological characteristics, do not raise difference safety or effectiveness questions and data demonstrates that the R:GEN is as safe and effective as the predicate device for the same intended use. The R:GEN is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design and dimensions, and identical materials as the device cleared in K153769.

The differences in technological characteristics from the predicate include using the same laser technology to provide additional treatment patterns and the use of the Real Time Feedback (RTF) Contact Lens. The subject device offers additional laser treatment patterns including single, square, circle and 2x2 Combo while the predicate device provided a single spot treatment pattern.

The maximum laser energy per pulse for the subject device is lower than the predicate device. The predicate device was designed to deliver a single pulse to the patient with no limitations on the number of pulses to be delivered during a treatment session. The subject device delivers a maximum of 15 pulses per treatment.

The R:GEN subject to this 510(k) has undergone testing to ensure the device is as safe and effective as the predicate for the intended use.

PERFORMANCE DATA

The R:GEN substantially conforms to the performance standards for light emitting products (21 CFR 1040). Bench testing was performed in accordance with IEC 60825-1 *Safety of laser products - Part 1: Equipment classification, and requirement* and IEC 60601-2-22 *Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.*

Bench Testing

The following tests were performed to demonstrate safety and performance based on current industry standards:

- Biocompatibility testing of patient contacting material in compliance to ISO 10993-1, ISO 10993-5, and ISO 10993-10
- Sterilization testing and shelf life validation of the RTF Sensor in compliance to ISO 11737-1, ISO 10993-7, ISO 11135, and ASTM F1980-16

- Software Verification and Validation were conducted in compliance to IEC 60601-1 and IEC 62304. Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Major" level of concern, since a failure or latent flaw could indirectly result in death or serious injury of the patient or operator through incorrect or delayed information or through the action of a care provider.
- Electromagnetic Compatibility (EMC) and Electrical Safety testing in compliance to IEC 60601-1, IEC 60601-1-6, IEC 60601-2-22, IEC 60825-1, and IEC/EN 60601-1-2

Animal Testing

An animal studies were performed with the R:GEN that established that the use of subject device wounds RPE cells. Additional published animal studies showing the safety and effectiveness of the subject were provided.

Clinical Evidence

Published clinical performance testing established that the subject device performs as intended in the treatment of CSME.

CONCLUSION

Based on the testing performed, including biocompatibility, sterilization, shelf life validation, software verification and validation, EMC and electrical safety, bench performance testing, animal testing, and published clinical evidence, it can be concluded that the subject device is able to perform equivalently to the predicate device. The R:GEN has the same indications for use, and technological characteristics, that do not raise different questions of safety and effectiveness and therefore is assessed to be substantially equivalent to the predicate device.