DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 5, 2016

Lutronic, Inc.
Jhung Won Vojir, PhD
VP of Quality and Regulatory Affairs
6 Neshaminy Interplex, Suite 100
Trevose, PA 19053

Re: K153769
Trade/Device Name: R:GEN Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 26, 2016
Received: August 25, 2016

Dear Dr. Vojir:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
R:GEN Laser System

Indications for Use *(Describe)*
The R:GEN Laser System is indicated for use by an opthalmic 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

**510(k) Summary**
**Lutronic Corporation R:GEN Laser System**

This 510(k) Summary is being submitted in accordance with 21 CFR § 807.92.

## 1. General Information

| | |
|---|---|
| Applicant: | Lutronic Corporation<br><br>219 Sowon-ro<br>Haengsin-dong, Deogyang-gu<br>Goyang-si, Gyeonggi-do 410-220<br>Republic of Korea<br>Tel: (82) 31-908-3440<br>Fax: (82) 31-907-3440 |
| Contact Person: | Jhung Won Vojir, Ph.D.<br>VP of Quality and Regulatory Affairs<br><br>Lutronic Corporation<br>Six Neshaminy Interplex, Suite 100<br>Trevose, PA 19053<br>Telephone: 215-205-2219<br>Fax: 609-488-6958<br>Email: jvojir@lutronic.com |
| Summary Preparation Date: | October 5, 2016 |

## 2. Names

| | |
|---|---|
| Trade Name: | R:GEN Laser System |
| Common Name: | Laser, Ophthalmic |
| Classification Name: | Ophthalmic Laser<br>Product Code: HQF<br>21 CFR § 886.4390<br>Panel: Ophthalmic Devices |

## 3. Predicate Device

The 2RT Laser System is a surgical instrument for performing retinal procedures in the treatment of Clinically Significant Macular Edema (CSME).

| | |
|---|---|
| **510(K) Number** | K122202 |
| **Company Name** | Ellex Medical Pty. Ltd. |
| **Device Name** | Ellex 2RT Ophthalmic Laser System (Model LR1532) |
| **Classification Regulation** | 21 CFR § 886.4390 |
| **Classification Name** | Ophthalmic Laser |
| **Product Code** | HQF |
| **Product Code Descriptor** | Laser, Ophthalmic |

## 4. Device Description

The R:GEN Laser System is a surgical laser instrument for use by ophthalmic physicians for performing selective retinal therapy (SRT) for treatment of Clinically Significant Macular Edema (CSME) which is a condition secondary to Diabetic Retinopathy. It is designed for use in a clinic or outpatient facility, or in Retinal Specialist's practice.

The R:GEN Laser System 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 R:GEN Laser System consists of a main laser, an optical fiber, delivery system including slit lamp, and a footswitch. The graphic user interface (GUI) screen of the control panel is equipped with an LCD (liquid crystal display) touch screen so that operators can easily adjust parameters for optimal settings. The software included provides all the functions, which are necessary to use the device.

The GUI screen of the control panel allows the operator to set the treatment parameters, such as the laser energy for each patient. The GUI screen of the control panel also displays useful information about the system during operation. During operation of the R:GEN Laser System, all system functions are continuously monitored internally by a micro-controller and displayed to the operator.

## 5. Indications for Use

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).

## 6. Substantial Equivalence

The R:GEN Laser System is substantially equivalent (SE) to the legally marketed Ellex 2RT Laser System that is the subject of 510(k) K122202.

| Manufacturer | | Lutronic Corporation | Ellex Medical Pty. Ltd. |
|---|---|---|---|
| **Device** | | R:GEN Laser System | 2RT (Model number LR1532) Ophthalmic Laser System |
| **510(k) #** | | K153769 | K122202 |
| **Indication for Use** | | 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:<br>• 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:<br>• Clinically Significant Macular Edema (CSME) |
| **Laser Type** | | Q-switched Nd:YLF Laser | Q-switched Nd:YAG Laser |
| **Laser Wavelengths** | | 527 nm (green) | 532 nm (green) |
| **Laser Energy** | | 0.03 mJ to 0.4 mJ | 0.1 mJ to 0.6 mJ |
| **Pulse Duration** | | 1.7µs | 3 ns |
| **Spot Size** | | 200 µm | 400 µm |
| **Aiming Beam** | | 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 |
| **Laser Delivery Modes** | | Single spot | Single spot |
| **FDA Classifications** | **FDCA** | Class II (special controls) 21 CFR § 886.4390 | Class II (special controls) 21 CFR § 886.4390 |
| | **RCHSA** | Class III B | Class III B |
| **GUI Screen of the Control Panel** | | Touch LCD Module | Touch LCD Module |

| | | |
|---|---|---|
| **Emission Control** | Footswitch | Footswitch |
| **Dimensions of Laser** | 340 mm (W) x 534.5 mm (L) x 619.5 mm (H) | 400 mm (W) x 625 mm (L) x 445 mm (H) |
| **Weight of Laser** | 52.62 kg | 48 kg |
| **Electrical Rating** | AC100-240V, 50/60Hz, Power Consumption 300VA | AC 100-240V, 50/60 Hz, Power Consumption 60W |

**7. Performance Data**

The Company's Performance Data for the R:GEN Laser System is as follows:

**Bench Testing**

Bench testing establish the accuracy of laser spot diameter, pulse duration and energy in laser exposure mode. The R:GEN Laser System bench testing meets all the device specifications and complies with all applicable standards, including ISO 13485:2003, AAMI / ANSI ES 60601-1:2005/(R)2012 and A1:2012, IEC 60601-2-22 Third Edition 2007-05 and IEC 60825-1 Edition 2.0 2007-03.

**Animal Testing**

There were two animal studies conducted with R:GEN laser with the objective to evaluate the retinal effects of SRT in two animal models – *in vivo* mice and *ex vivo* porcine – and to demonstrate that R:GEN laser SRT is effective in selectively destroying RPE cells without collateral damage to neural retina or choroid with the goal of inducing RPE cell regeneration. Both studies were conducted in full compliance with the good laboratory practices (GLPs).

**Clinical Testing**

Two separate clinical studies investigated the safety and effectiveness of the selective retina therapy (SRT) for clinically significant diabetic macular edema (DME).

Twenty-three eyes of 21 Korean subjects with clinically significant DME were treated with SRT and followed for 6 months. The mean subject age was 63.3 years with 14 females and 7 males, with type 2 diabetes and clinically significant DME according to ETDRS criteria. The subjects ranged from 48 to 77 years of age. The number of treatment laser spots was 41.1 (Standard Deviation (SD) = 18.8, range 12 to87 laser spots), and mean treatment pulse energy was 92.1 µJ (SD=8.2, 75 µJ to 130 µJ).

Mean visual acuity improved significantly between baseline and 6 months, from 0.35 logMAR to 0.23 logMAR ($p$=0.002). After 6 months, 29.4% of SRT-treated eyes gained ≥2 ETDRS lines from baseline, while 41.2% gained 1-2 ETDRS lines, and 17.6% remained stable (<1 ETDRS line change). Conversely, only two eyes (11.8%) lost ≥1 ETDRS lines from baseline. Although there was no significant change in central macular thickness (CMT) ($p$>0.05), maximum macular thickness (MMT) decreased from 465.8 ± 87.4 µm to 434.3 ± 83.9 µm ($p$=0.006), and mean macular sensitivity increased from 20.8 ± 3.4 dB to 22.5 ± 3.5 dB ($p$=0.02). No eyes experienced severe loss of vision (≥2 ETDRS lines) at the 6-month follow-up visit. Individual eyes demonstrated no scotomatous changes in macular sensitivity within the central 10º over 6 months. No treatment-related complications or adverse events were noted in this study.

A study involving thirty-nine eyes of 39 Caucasian subjects with previously untreated non-ischemic DME was performed. The mean subject age was 63.9 year with 16 females and 23 males. The mean number of applied laser spots was 35.2 (SD=24, range 11 to 125 laser spots). The mean treatment pulse energy was 247 µJ (SD=50, range 200 µJ to 325µJ). The mean best-corrected ETDRS visual acuity (BCVA) improved from 43.7 letters (SD=9.1) at baseline to 46.1 letters (SD=10. 5) at the 6-month follow-up ($p$=0.02). BCVA improved (>5 letters) or remained stable (±5 letters) in 84% of eyes. Thirteen percent (13%) of eyes improved by ≥10 letters, while 16% of eyes lost more than 5 letters. There was no severe loss of vision (≥15 letters). Overall, retinal thickness, hard exudates, and leakage in fundus fluorescein angiography (FFA) did not change significantly ($p$>0.05), while improvement of BCVA correlated with a reduction of hard exudates ($p$=0.01) and central retinal thickness ($p$=0.01). No complications or adverse events were noted during or after treatment, and no patients reported any adverse effects related to SRT or pain during laser application.

**8. Conclusion**

The R:GEN Laser System and the legally marketed 2RT Laser System cleared under 510(k) number K122202, have the same intended use and Indications for Use statement. While the technological characteristics differ between the two systems, the differences have been established to be minor. Performance testing data established that the R:GEN Laser System is as safe and effective as the legally marketed predicate device and that the R:GEN Laser System does not raise any different questions of safety and effectiveness than the predicate. On this basis and in accordance with 21 CFR § 807.100(b), the R:GEN Laser System is substantially equivalent to the 2RT Laser System and can be legally marketed in the US.