510(k) Summary for the
Lutronic Corporation CLARITY LPC Laser System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

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Summary Preparation Date: October 21, 2013

2. **Names**

Trade Name: CLARITY LPC Laser System

Common Name: Dermatology Laser

Classification Name: Laser Instrument, Surgical, Powered
Product Code: GEX
Panel: General & Plastic Surgery
Regulatory Class: II
Regulation Number: 21 CFR 878.4810

3. **Predicate Devices**

The CLARITY LPC Laser System is substantially equivalent to the Candela Corporation GentleMAX Family of Laser Systems (K112715).

4. Device Description

The CLARITY LPC Laser System contains two separate laser resonators, an Alexandrite resonator and an Nd: YAG (Neodymium-doped Yttrium Aluminum Garnet) resonator which generates pulsed laser energy at the nominal wavelength 755 nm and 1064 nm, respectively. The outputs of each laser generator and the aiming beam are optically combined on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system for either the 755 nm or 1064 nm wavelength.

The control panel is equipped with an LCD touch screen so that users can easily adjust parameters for optimal settings. The software included provides all the function which is necessary to use the device.

The CLARITY LPC laser system is configured with an ICD (Intelligent Cooling Device) skin cooling device.

The CLARITY LPC Laser System delivers laser energy with various pulse durations from 0.35 milliseconds to 300 milliseconds. The output of this laser is delivered to the area of treatment by means of a lens coupled user replaceable optical fiber with a treatment handpiece attached to its distal end. A trigger switch (finger switch or footswitch) is used to control the delivery of laser pulses. The user may choose to deliver a single pulse each time the trigger switch is depressed, or pulses may be delivered repetitively as long as the switch is depressed, at repetition rates up to 10 pulses per second (depending on the chosen pulse duration).

The laser output energy is delivered via an optical fiber to a handpiece which produces circular beams with diameters from 2 to 20 millimeters on the skin.
Operators of the laser select parameters such as desired energy density (fluence) level and repetition rate and monitor operation via a touch screen and display panel. The touch screen panel can also be used to enable or disable the triggering of the laser, to initiate the calibration feature and to obtain feedback from the system.

5. Indications for Use

The CLARITY LPC Laser System is indicated for the following:

<u>755nm</u>
The CLARITY LPC Laser System is indicated for temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I-VI) including tanned skin.
Treatment of benign pigmented lesions.
Treatment of wrinkles. The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

1064nm

The CLARITY LPC Laser System is indicated for the removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.

The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Treatment of wrinkles.

6. Substantial Equivalence

The CLARITY LPC Laser System is substantially equivalent to the GentleMAX Family of Laser Systems cleared in K112715. The CLARITY LPC Laser System has the same technological characteristics as the predicate device. Both devices have two separate laser resonators, an Alexandrite resonator and an Nd: YAG (Neodymium-doped Yttrium Aluminum Garnet) resonator which generates pulsed laser energy at the nominal wavelength of 755 nm and of 1064 nm, respectively.

Additionally, they have the same intended uses, similar treatment parameters, similar operating principles, including similar spot sizes and the same maximum delivered fluence as the predicate device. On the basis of similarities in methods of assembly, method of operation, and intended uses, CLARITY LPC Laser System is substantially equivalent to the predicate device.

Device	CLARITY LPC Laser System	GentleMAX Family of Laser Systems
Manufacturer	Lutronic Corporation	Candela Corporation
510(k) #	K130199	K112715
Wavelength	755 nm	755 nm
Laser Source	Alexandrite	Alexandrite
Indication	The CLARITY LPC Laser System is indicated for temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I-VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias)	The GentleMAX Family of Laser Systems is indicated for temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. On all skin types (Fitzpatrick I-VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias)

	Skin Type	Pulse Duration	Spot Size	Fluence	Skin Type	Pulse Duration	Spot Size	Fluence
Treatment Parameters for hair removal	I – II	3 ms	8 mm	30-40 J/cm^2	I – II	3 ms	8 mm	30-40 J/cm^2
		3 ms	10 mm	26-34 J/cm^2		3 ms	10 mm	25-35 J/cm^2
		3 ms	12 mm	26-30 J/cm^2		3 ms	12 mm	26-36 J/cm^2
						3 ms	15 mm	20-40 J/cm^2
						3 ms	18 mm	14-20 J/cm^2
	III	3 ms	8 mm	26-40 J/cm^2	III	3 ms	8 mm	25-40 J/cm^2
		3 ms	10 mm	15-30 J/cm^2		3 ms	10 mm	15-30 J/cm^2
		3 ms	12 mm	18-26 J/cm^2		3 ms	12 mm	18-30 J/cm^2
		3 ms	15 mm	16-19 J/cm^2		3 ms	15 mm	16-25 J/cm^2
		3 ms	18 mm	10-13 J/cm^2		3 ms	18 mm	10-16 J/cm^2
	IV	3 ms	8 mm	20-30 J/cm^2	IV	3 ms	8 mm	20-30 J/cm^2
		3 ms	10 mm	15-24 J/cm^2		3 ms	10 mm	15-25 J/cm^2
		3 ms	12 mm	16-20 J/cm^2		3 ms	12 mm	16-20 J/cm^2
		3 ms	15 mm	10-15 J/cm^2		3 ms	15 mm	10-20 J/cm^2
		3 ms	18 mm	8-11 J/cm^2		3 ms	18 mm	8-16 J/cm^2
	V	3 ms	8 mm	20-24 J/cm^2	V	3 ms	8 mm	20-25 J/cm^2
		3 ms	10 mm	16-20 J/cm^2		3 ms	10 mm	16-20 J/cm^2
		3 ms	12 mm	14-20 J/cm^2		3 ms	12 mm	14-20 J/cm^2
		3 ms	15 mm	10-15 J/cm^2		3 ms	15 mm	10-20 J/cm^2
		3 ms	18 mm	6-11 J/cm^2		3 ms	18 mm	6-16 J/cm^2
	VI	3 ms	8 mm	20-24 J/cm^2	VI	3 ms	8 mm	20-25 J/cm^2
		3 ms	10 mm	16-20 J/cm^2		3 ms	10 mm	16-20 J/cm^2
		3 ms	12 mm	10-20 J/cm^2		3 ms	12 mm	10-20 J/cm^2
		3 ms	15 mm	6-13 J/cm^2		3 ms	15 mm	6-20 J/cm^2
	VI	3 ms	18 mm	6-10 J/cm^2	VI	3 ms	18 mm	6-16 J/cm^2
	Skin Type	Pulse Duration	Spot Size	Fluence	Skin Type	Pulse Duration	Spot Size	Fluence
Treatment Parameters for pigmented lesions	I – IV (solar lentigines, benign melanocytic nevi)	3 ms	8 mm	30-40 J/cm^2	I – IV (solar lentigines, benign melanocytic nevi)	3 ms	8 mm	30-40 J/cm^2

	I – IV (Seborrheic keratoses)	3 ms	10 mm	30-40 J/cm^2	I – IV (seborrheic keratoses)	3 ms	10 mm	80-100 J/cm^2
		3 ms	12 mm	80-100 J/cm^2		3 ms	12 mm	
Treatment Parameters for wrinkles	Skin Type	Pulse Duration	Spot Size	Fluence	Skin Type	Pulse Duration	Spot Size	Fluence
	I – IV	3 ms	12 mm	26-30 J/cm^2	I – IV	3 ms	12 mm	25-40 J/cm^2
Fluence	Max 600 J/cm^2				520 J/cm^2			
Pulse Width	0.35 ms to 300 ms				0.25 ms to 300 ms			
Average Power (Watts)	55.95 W				50.84 W			
Maximum Energy Delivered (J)	Max 55.95 J (Pulse width: 300 ms @ 18 mm)				Max 50.87 J (Pulse width: 300 ms @ 18 mm)			
Pulse Rate	Up to 10 Hz				Up to 10 Hz			
Spot Size	2, 3, 5, 8, 10, 12, 15, 18, 20 mm				6, 8, 10, 12, 15, and 18 mm			
Delivery System	Optical fiber with handpiece				Optical fiber with handpiece			
Cooling	Water to Air				Water to Air			

Predicate Comparison Table for 1064nm

Device	CLARITY LPC Laser System	GentleMAX Family of Laser Systems
Manufacturer	Lutronic Corporation	Candela Corporation
510(k) #	K130199	K112715.
Wavelength	1064 nm	1064 nm
Laser Source	Nd: YAG	Nd: YAG
Indications	The CLARITY LPC Laser System is indicated for the removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques. The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would	The GentleMAX Family of Laser Systems is indicated for the removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques. The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

	potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles.				Treatment of wrinkles.			
Treatment Parameters for hair removal	Skin Type	Pulse Duration	Spot Size	Fluence	Skin Type	Pulse Duration	Spot Size	Fluence
	I – II	20 ms	8 mm	90-100 J/cm^2	I – II	3, 10, 20 ms	8 mm	90-100 J/cm^2
			10 mm	70-80 J/cm^2			10 mm	70-80 J/cm^2
			12 mm	60-70 J/cm^2			12 mm	60-70 J/cm^2
			15 mm	40-44 J/cm^2			15 mm	40-44 J/cm^2
			18 mm	26-30 J/cm^2			18 mm	26-30 J/cm^2
	III	20 ms	8 mm	80-90 J/cm^2	III	3, 10, 20 ms	8 mm	80-90 J/cm^2
			10 mm	50-70 J/cm^2			10 mm	50-70 J/cm^2
			12 mm	40-60 J/cm^2			12 mm	40-60 J/cm^2
			15 mm	30-40 J/cm^2			15 mm	30-40 J/cm^2
			18 mm	24-30 J/cm^2			18 mm	24-30 J/cm^2
	IV	20 ms	8 mm	60-70 J/cm^2	IV	3, 10, 20 ms	8 mm	60-70 J/cm^2
			10 mm	40-50 J/cm^2			10 mm	40-50 J/cm^2
			12 mm	20-45 J/cm^2			12 mm	20-46 J/cm^2
			15 mm	20-30 J/cm^2			15 mm	20-30 J/cm^2
			18 mm	14-20 J/cm^2			18 mm	14-20 J/cm^2
	V	20 ms	8 mm	50-60 J/cm^2	V	3, 10, 20 ms	8 mm	50-60 J/cm^2
			10 mm	30-50 J/cm^2			10 mm	30-50 J/cm^2
			12 mm	18-30 J/cm^2			12 mm	18-30 J/cm^2
			15 mm	10-30 J/cm^2			15 mm	10-30 J/cm^2
			18 mm	6-20 J/cm^2			18 mm	6-20 J/cm^2
	VI	20 ms	8 mm	40-50 J/cm^2	VI	3, 10, 20 ms	8 mm	40-50 J/cm^2
			10 mm	30-40 J/cm^2			10 mm	30-40 J/cm
			12 mm	18-30 J/cm^2			12 mm	18-30 J/cm^2
			15 mm	6-30 J/cm^2			15 mm	6-30 J/cm^2
			18 mm	6-20 J/cm^2			18 mm	6-18 J/cm^2

Treatment Parameters for pigmented lesions	Lesion	Pulse Duration	Spot Size	Fluence	Lesion	Pulse Duration	Spot Size	Fluence
	Telangiectasia < 1 mm	40-50 ms	3 mm	Start with 220 J/cm^2	Telangiectasia < 1 mm	40-60 ms	3 mm	Start with 220 J/cm^2
	Telangiectasia (Facial) Vessels < 1 mm	30 ms	3 mm	Start with 130 J/cm^2	Telangiectasia (Facial) Vessels < 1 mm	30 ms	3 mm	Start with 130 J/cm^2
	Telangiectasia (Leg) Vessels < 1.5 mm	40-50 ms	3 mm	Start with 200 J/cm^2	Telangiectasia (Leg) Vessels < 1.5 mm	40-60 ms	3 mm	Start with 200 J/cm^2
	Telangiectasia (Leg) Vessels 1.5-3.0 mm	50 ms	3 mm	Start with 180 J/cm^2	Telangiectasia (Leg) Vessels 1.5-3.0 mm	60 ms	3 mm	Start with 180 J/cm^2
Treatment Parameters for wrinkles	Area	Pulse Duration	Spot Size	Fluence	Area	Pulse Duration	Spot Size	Fluence
	Face & Neck	50 ms	10 mm	50 J/cm^2	Face & Neck	50 ms	10 mm	50 J/cm^2
	Forehead	50 ms	10 mm	40-50 J/cm^2	Forehead	50 ms	10 mm	40-50 J/cm^2
Fluence	Max. 600 J/cm^2				Max. 600 J/cm^2			
Pulse Width	0.35 ms to 300 ms				0.25 ms to 300 ms			
Average Power (Watts)	96.08 W				76.30 W			
Maximum Energy Delivered (J)	Max 96.08 J (Pulse width: 300 ms @ 18 mm)				Max 76.30 J (Pulse width: 300 ms @ 18 mm)			
Pulse Rate	Up to 10 Hz				Up to 10 Hz			

Spot Size	2, 3, 5, 8, 10, 12, 15, 18, 20 mm	1.5, 3, 6, 8, 10, 12, 15, and 18mm
Delivery System	Optical fiber with handpiece	Optical fiber with handpiece
Cooling	Water to Air	Water to Air

7. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Lutronic Corporation
Jhung Won Vojir, M.S, Ph.D.
Global Regulatory Officer
6 Neshaminy Interplex, Suite 100
Trevose, Pennsylvania 19053

November 22, 2013

Re: K130199
Trade/Device Name: CLARITY LPC Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 18, 2013
Received: October 18, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130199

Device Name: CLARITY LPC Laser System

Indications for Use:

755nm

The CLARITY LPC Laser System is indicated for temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I-VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles.

The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

1064nm

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The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Treatment of wrinkles.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use ____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.11.22 09:15:56 -05'00'

(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number K130199