March 26, 2021

Lutronic Corporation
Jhung Vojir
Chief Operating Officer
Lutronic Center, 219, Sowon-Ro
Deogyang-Gu, Goyang-si, Geonggi-do 410220
Korea, South

Re: K203788
Trade/Device Name: DermaV 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: December 23, 2020
Received: December 28, 2020

Dear Jhung 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. 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 post-marketing 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,

For Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203788

Device Name
DermaV Laser System

Indications for Use *(Describe)*
1064 nm
The DermaV Laser System is indicated for stable long term or permanent hair reduction and for treatment of PFB (Pseudofolliculitis Barbae) on all skin types, Fitzpatrick I – VI, including tanned skin. 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 1064 nm laser is also indicated for coagulation and hemostasis of soft tissue, for hemostasis of vascular lesions such as but not limited to port wine stains, hemangiomna, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The 1064 nm laser system is also indicated for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, (significant reduction in the intensity of black and/or blue- black tattoos) and plaques. The 1064 nm Laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

532 nm
For coagulation and hemostasis of vascular and cutaneous lesions in dermatology, including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions [nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink)]; verrucae; skin tags; keratoses; plaques; and cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

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

Lutronic Corporation
DermaV Laser System

510(k) Owner
Lutronic Corporation
219, Sowon-Ro
Deogyang-Gu, Goyang-Si, KR 410220

Submission Correspondent
Jhung Won Vojir, PhD
Chief Operating Officer, Lutronic Aesthetics, Inc.
19 Fortune Drive
Billerica, MA 01821
Tel: 888-588-7644

Date Prepared: March 24, 2021

Trade Name of Device
DermaV Laser System

Common or Usual Name
Surgical Laser

Classification Name
Laser Surgical Instrument for Use in General and Plastic Surgery and Dermatology;
21 C.F.R. 878.4810
Class II
Product Code: GEX

Predicate Devices
Primary predicate: Lutronic Corporation CLARITY II cleared in K183566
Secondary predicate: Cutera Family of Coolglide Aesthetic Lasers cleared in K153671

Device Description
The DermaV laser system contains a Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) resonator which generates pulsed laser energy at the nominal wavelengths of 1064 nm and 532 nm using KTP. The outputs of each laser generator and the aiming beam (635 nm) 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 532 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 DermaV laser system is comprised of three main components: system main body, optical fiber with handpiece, and footswitch.

The DermaV laser system emits laser energy at 532 nm or 1064 nm via a handpiece attached to an optical fiber. The DermaV laser system can be configured with an ICD (Intelligent Cooling Device) skin cooling device. The pulsed beam is directed to the treatment zone through a lens-coupled optical fiber attached to a handpiece. When the beam contacts human tissue, the energy of the beam is absorbed by the tissue, resulting in a very rapid and highly localized temperature increase in the target. The short but swift temperature increase causes selective heating and destroys of the target materials into smaller particles.

Indications for Use

1064 nm

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The 1064 nm laser is also indicated for coagulation and hemostasis of soft tissue, for hemostasis of vascular lesions such as but not limited to port wine stains, hemangiomna, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The 1064 nm laser system is also indicated for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, (significant reduction in the intensity of black and/or blue- black tattoos) and plaques. The 1064 nm Laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

532 nm

For coagulation and hemostasis of vascular and cutaneous lesions in dermatology, including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions [nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink)]; verrucae; skin tags; keratoses; plaques; and cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

Nonclinical Performance Testing

The DermaV Laser System was tested for electrical safety and found to be in conformance with IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and for electromagnetic compatibility and found to be in conformance with IEC 60601-1-2 Medical electrical equipment Part 1-2 General requirements for basic safety and essential performance- Collateral standard: Electromagnetic Disturbances-Requirements and tests.

The DermaV Laser System has been tested and found in conformance with IEC 60825-1 Safety of laser products-Part 1: Equipment classification and requirements.

The DermaV Laser System was tested for biocompatibility and is in conformance with ISO 10993-1 "Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process ", ISO 10993-5 "Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity ", and ISO 10993-10 "Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization".

Clinical Performance Testing

Clinical performance testing was not needed for this submission; therefore, no clinical tests were submitted.

Comparison with the Predicate Devices

The 1064 nm and 532 nm functionality of the DermaV Laser System utilizes technology similar to the predicate devices. The DermaV Laser System and the Lutronic CLARITY II Laser System have the same intended use and similar technological characteristics for the 1064 nm functions and the Cutera Coolglide Laser System has the same intended use and similar technological characteristics for the 532 nm functions. Performance testing provided demonstrates that the device can function safely and effectively for its intended use. Differences in the proposed device's technical features, such as software, biocompatibility, and laser output parameters, do not raise new types of questions regarding the device's safety and efficacy for its indications for use.

Table 1: DermaV Laser System Substantial Equivalence (1064 nm Functions)

Characteristic	DermaV Laser System	CLARITY II Laser System
Manufacturer	Lutronic Corporation	Lutronic Corporation
510(k) Number	K203788	K183566
Product Code	GEX	GEX
Laser Wavelength	1064 nm, 532 nm	1064 nm, 755 nm
Indications for Use at 1064 nm	1064 nm: The DermaV Laser System is indicated for stable long term or permanent hair reduction and for treatment of PFB (Pseudofolliculitis Barbae) on all skin types, Fitzpatrick I – VI, including tanned skin. 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 1064 nm laser is also indicated for coagulation and hemostasis of soft tissue, for	1064 nm: The DermaV Laser System is indicated for stable long term or permanent hair reduction and for treatment of PFB (Pseudofolliculitis Barbae) on all skin types, Fitzpatrick I – VI, including tanned skin. 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 1064 nm laser is also indicated for coagulation and

	hemostasis of vascular lesions such as but not limited to port wine stains, hemangiomna, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The 1064 nm laser system is also indicated for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, (significant reduction in the intensity of black and/or blue-black tattoos) and plaques. The 1064 nm Laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.	hemostasis of soft tissue, for hemostasis of vascular lesions such as but not limited to port wine stains, hemangiomna, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The 1064 nm laser system is also indicated for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, (significant reduction in the intensity of black and/or blue- black tattoos) and plaques. The 1064 nm Laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.
Laser Type	Pulsed Solid State Laser	Pulsed Solid State Laser
Beam Delivery	Optical Fiber with Handpiece	Optical Fiber with Handpiece
Aiming Beam	635 nm	515-535 nm
Pulse Energy	1064 nm: Max 100 J	1064 nm: Max 100 J
Pulse Width	0.1 – 60 ms	0.1 - 300 ms
Max Fluence (J/cm^2)	300	600
Pulse Rate	0.5-10 Hz	0.5-10 Hz
CDRH Laser Class	IV	IV
User Interface	Touch LCD	Touch LCD
Spot Size	2, 3, 5, 7, 8, 10, 12, 14, 16 nm	2, 3, 5, 8, 10, 12, 15, 16, 18, 20, 22, 24 nm
Emission Control	Finger Switch or Footswitch	Finger Switch or Footswitch
Integrated Cooling	Yes	Yes

Table 2: DermaV Laser System Substantial Equivalence (532 nm Functions)

Characteristic	**DermaV Laser System**	**Family of Coolglide Aesthetic Lasers**
Manufacturer	Lutronic Corporation	Cutera, Inc.
510(k) Number	K203788	K153671
Product Code	GEX	GEX
Laser Wavelength	1064 nm, 532 nm	1064 nm, 532 nm
Indications for Use at 532 nm	532 nm For coagulation and hemostasis of vascular and cutaneous lesions in dermatology, including, but not	532 nm For coagulation and hemostasis of vascular and cutaneous lesions in dermatology,

	limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions [nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink)]; verrucae; skin tags; keratoses; plaques; and cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).	including, but not limited to, the following general categories: vascular lesions [angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions [nevi, lentigines, chloasma, café-au-lait, tattoos (red and green ink)]; verrucae; skin tags; keratoses; plaques; and cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).
Laser Type	Pulsed Solid State Laser	Flash Pumped Solid State Rod
Beam Delivery	Optical Fiber with Handpiece	Optical Fiber with Handpiece
Aiming Beam	635 nm	630-680 nm
Pulse Energy	532 nm: Max 13.5 J	532 nm: Max 12 J
Pulse Width	0.3 - 40 ms	1.5 - 40 ms
Pulse Rate	0.5-10 Hz	$\leq$ 10 Hz
Max Fluence (J/cm^2)	50	42
CDRH Laser Class	IV	IV
User Interface	Touch LCD	Touch LCD
Spot Size	2, 3, 5, 7, 8, 10, 12, 14, 16 nm	2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 nm
Emission Control	Finger Switch or Footswitch	Finger Switch or Footswitch
Integrated Cooling	Yes	Yes

Conclusions

The DermaV Laser System's indications for use and technological characteristics do not raise new types of questions regarding safety and efficacy when compared to the predicates. Based on its technical characteristics, design, functional features, performance test data, and its indications for use as listed above, the DermaV Laser System is considered to be substantially equivalent to the predicate devices.