June 19, 2018

Lutronic Corporation
Dr. James Childs
Clinical Science Director,
Lutronic Global
19 Fortune Drive
Billerica, MA 01821

Re: K173700
Trade/Device Name: PICOPLUS 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: May 18, 2018
Received: May 18, 2018

Dear Dr. James Childs:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173700

Device Name
PICOPLUS Laser System

Indications for Use *(Describe)*

The PICOPLUS Laser System is indicated for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery as follows:

The 1064 nm wavelength and 450 pico-second pulse width of the PICOPLUS system is indicated for:
• Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple.
• Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

The 532 nm wavelength and 450 pico-second pulse width of the PICOPLUS system is indicated for:
• Removal of tattoos for Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange.
• Treatment of benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

The 1064 nm wavelength and nanosecond pulse width of the PICOPLUS system is indicated for:
• Treatment of benign pigmented lesions on Fitzpatrick skin type I-VI
• Removal of dark and multi-colored tattoos containing dark colored tattoo inks on Fitzpatrick skin types 1-VI

The 532 nm wavelength and nanosecond pulse width of the PICOPLUS system is indicated for:
• Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV
• Removal of lighter colored tattoo inks, including red and yellow inks, on Fitzpatrick skin types I-III

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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6. 510(k) SUMMARY OR STATEMENT

The Company's 510(k) Summary for the PICOPLUS Laser System is as follows:

510(k) Summary

Lutronic Corporation PICOPLUS Laser System
This 510(k) Summary is being submitted in accordance with 21 CFR § 807.92.

1. General Information

Applicant:	Lutronic Corporation Lutronic Center, 219 Sowon-ro Haengsin-dong, Deogyang-gu Goyang-si, Gyeonggi-do 410-220 Republic of Korea Tel: (82) 31-908-3440 FAX: (82) 31-907-3440
Contact Person:	James J Childs, PhD Clinical Science Director Lutronic Corporation 19 Fortune Drive Billerica, MA 01821 Tel: 508-446-1126 FAX: 781-262-0647 Email: jchilds@lutronic.com
Summary Preparation Date:	June 18, 2018

2. Names

Trade Name: PICOPLUS Laser System

Common Name: Laser Surgical Instrument

Classification Name:	Powered Laser Surgical Instrument Product Code: GEX 21 CFR § 878.4810 Panel: General & Plastic Surgery

3. Predicate Devices

Cutera Enlighten III Laser System (K172077)
Quanta System S.P.A. Discovery Pico Family (K163222)

4. Device Description

The PICOPLUS Laser System is a surgical laser instrument for cutaneous laser treatment. The PICOPLUS Laser System is designed and manufactured in accordance with 21 CFR 820 (with emphasis on 820.30) and 21 CFR 1040 for medical devices in order to insure user safety and durability of use.
The PICOPLUS Laser System is a laser system, delivering energy at wavelengths of 1064 nm and 532 nm, both at pulse durations of 450 picoseconds (ps) and 2 nanoseconds (ns). The laser system is comprised of a system console, an articulated arm and attached handpieces.

5. Indications for Use

The PICOPLUS Laser System is indicated for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery as follows:

The 532 nm wavelength and 450 pico-second pulse duration of the PICOPLUS system is indicated for

- Removal of tattoos for Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange.
- Treatment of benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

The 1064 nm wavelength and 450 pico-second pulse duration of the PICOPLUS system is indicated for:

- Removal of tattoos on all skin types (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple.
- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

The 1064 nm wavelength and nanosecond pulse duration of the PICOPLUS system is indicated for:

- Treatment of benign pigmented lesions on Fitzpatrick skin types I-VI
- Removal of dark and multi-colored tattoos containing dark colored tattoo inks on Fitzpatrick skin types I-VI

The 532 nm wavelength and nanosecond pulse duration of the PICOPLUS system is indicated for:

- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV
- Removal of lighter colored tattoo inks, including red and yellow inks, on Fitzpatrick skin types I-III

6. Substantial Equivalence

Tables 1a & 1b below compare the device specifications for each Indication for Use of the Subject and Predicate devices.

Table 1a. Comparison of IFUs and device specifications at Nanosecond Pulse Durations

(Note the Predicate device IFUs and device specifications table are repeated for side-by-side comparison to the Subject device's Handpiece 1 and 2.)

Comparison of device specifications at Nanosecond Pulse Duration											
Lutronic Corporation PICOPLUS Laser System						**Cutera Enlighten III**					
Handpiece	**Indications for Use**	**Wave-length**	**Max Pulse Energy**	**Spot Size**	**Fluence**	**Handpiece**	**Indications for Use**	**Wave-length**	**Max Pulse Energy**	**Spot Size**	**Fluence**
Handpiece 1 (2 ns)	Indicated for: • Treatment of benign pigmented lesions on Fitzpatrick skin type I-VI • Removal of dark and multi-colored tattoos containing dark colored tattoo inks on Fitzpatrick skin types 1-VI	1064 nm	800 mJ	2, 3, 4, 5, 6 mm	0.18~ 10 J/cm^2	Handpiece (2 ns)	Indicated for treatment of benign pigmented lesions on patients with all skin types (Fitzpatrick I-VI); tattoo removal for dark colored tattoo inks and for multicolored tattoos containing inks on patients with all skin types (Fitzpatrick I-VI)	1064 nm	800 mJ	2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 mm	10 J/cm^2 (range not available)
	Indicated for: • Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV • Removal of lighter colored tattoo inks, including red and yellow inks, on Fitzpatrick skin types I-III	532 nm	300 mJ	2.3, 3.3, 4.3, 5.3 mm	0.05~ 2.5 J/cm^2		Indicated for treatment of benign pigmented lesions for Fitzpatrick skin types I-IV; tattoo removal with lighter colored inks including red and yellow inks for Fitzpatrick skin types I-III	532 nm	400 mJ	2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 mm	2.5 J/cm^2 (range not available)

Table 1a. Comparison of IFUs and device specifications at Nanosecond Pulse Durations (Cont.)

Comparison of device specifications at Nanosecond Pulse Duration											
Lutronic Corporation PICOPLUS Laser System						**Cutera Enlighten III**					
Handpiece	**Indications for Use**	**Wave-length**	**Max Pulse Energy**	**Spot Size**	**Fluence**	**Handpiece**	**Indications for Use**	**Wave-length**	**Max Pulse Energy**	**Spot Size**	**Fluence**
Handpiece 2 (2 ns)	Indicated for: • Treatment of benign pigmented lesions on Fitzpatrick skin type I-VI • Removal of dark and multi-colored tattoos containing dark colored tattoo inks on Fitzpatrick skin types 1-VI	1064 nm	800 mJ	6, 7, 8, 9, 10 mm	0.07~ 2.8 J/cm^2	Handpiece (2 ns)	Indicated for treatment of benign pigmented lesions on patients with all skin types (Fitzpatrick I-VI); tattoo removal for dark colored tattoo inks and for multicolored tattoos containing inks on patients with all skin types (Fitzpatrick I-VI)	1064 nm	800 mJ	2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 mm	10 J/cm^2 (range not available)
	Indicated for: • Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV • Removal of lighter colored tattoo inks, including red and yellow inks, on Fitzpatrick skin types I-III	532 nm	300 mJ	4.3, 5.3, 6.5, 8 mm	0.02~ 2.0 J/cm^2		Indicated for treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-IV; tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III	532 nm	400 mJ	2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9, 10 mm	2.5 J/cm^2 (range not available)

Table 1b. Comparison of IFUs and device specifications at Picosecond Pulse Durations (Cont.)

(Note the Predicate device IFUs and device specifications table are repeated for side-by-side comparison to the Subject device's Handpiece 1 and 2.

Comparison of device specifications at Picosecond Pulse Duration											
Lutronic Corporation PICOPLUS Laser System						**Discovery Pico Family**					
Handpiece	**Indications for Use**	**Wave-length**	**Max Pulse Energy**	**Spot Size**	**Fluence (range)**	**Handpiece**	**Indications for Use**	**Wave-length**	**Max Pulse Energy**	**Spot Size**	**Fluence**
Handpiece 1 (450 ps)	Indicated for: • Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple.	1064 nm	800 mJ	3, 4, 5, 6 mm	0.18 - 5.6 J/cm^2	Handpiece (450 ps)	Indicated for removal of tattoos on all Fitzpatrick skin types I- VI with following colors: black, brown, green, blue, and purple. Indicated for treatment of benign pigmented lesions on Fitzpatrick types I-IV	1064 nm	800 mJ	3, 4.5, 6, 7.5 9, 10.5 mm	5.6 J/cm^2 (range not available)
	Indicated for: • Removal of tattoos for Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange. • Treatment of benign pigmented lesions removal for Fitzpatrick Skin Types I-IV	532 nm	300 mJ	3.3, 4.3, 5.3 mm	0.05 - 2.8 J/cm^2		Indicated for removal of tattoos on Fitzpatrick skin types I-III with the following colors: red, yellow and orange. Indicated for treatment of benign pigmented lesions on Fitzpatrick Skin Types I-IV	532 nm	300 mJ	3, 4.5, 6, 7.5 9, 10.5 mm	2.8 J/cm^2 (range not available)

Table 1b. Comparison of IFUs and device specifications at Picosecond Pulse Durations (Cont.)

Comparison of device specifications at Picosecond Pulse Duration											
Lutronic Corporation PICOPLUS Laser System						**Discovery Pico Family**					
Handpiece	**Indications for Use**	**Wave-length**	**Max Pulse Energy**	**Spot Size**	**Fluence (range)**	**Handpiece**	**Indications for Use**	**Wave-length**	**Max Pulse Energy**	**Spot Size**	**Fluence**
Handpiece 2 (450 ps)	Indicated for: • Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple. • Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV	1064 nm	800 mJ	6, 7, 8, 9, 10 mm	0.07 - 2.8 J/cm^2	Handpiece (450 ps)	Indicated for removal of tattoos on all Fitzpatrick skin types I-VI with following colors: black, brown, green, blue, and purple. Indicated for treatment of benign pigmented lesions on Fitzpatrick types I-IV	1064 nm	800 mJ	3, 4.5, 6, 7.5 9, 10.5 mm	5.6 J/cm^2 (range not available)
	Indicated for: • Removal of tattoos for Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange. • Treatment of benign pigmented lesions removal for Fitzpatrick Skin Types I-IV	532 nm	300 mJ	4.3, 5.3, 6.5, 8 mm	0.02 - 2.0 J/cm^2		Indicated for removal of tattoos on Fitzpatrick skin types I-III with the following colors: red, yellow and orange. Indicated for treatment of benign pigmented lesions on Fitzpatrick Skin Types I-IV	532 nm	300 mJ	3, 4.5, 6, 7.5 9, 10.5 mm	2.8 J/cm^2 (range not available)

The PICOPLUS Laser System shares the same indications for use, device operation, technical and functional capabilities. The devices' fluences for the 1064 nm and 532 nm wavelengths at both 450 ps and 2 ns pulse durations are all the same.

Therefore the handpieces of the Subject device are substantially equivalent to the corresponding handpieces of the Predicate devices for the Indications for Use.

7. Performance Data

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

Bench Testing
The PICOPLUS Laser System complies with all applicable standards, including ISO 13485:2003, ISO 60601-1 for electrical safety and IEC 60601-1-2 for electromagnetic compatibility.

Clinical Testing
No performance data has been provided since the PICOPLUS Laser System is equivalent to the previously cleared predicate devices with no new issues regarding safety and effectiveness.

8. Conclusion

The PICOPLUS Laser System and the legally marketed Cutera Enlighten III Laser System cleared under 510(k) number K172077 and the legally marketed Quanta System S.P.A. Discovery Pico Family cleared under 510(k) number K163222, 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 PICOPLUS Laser System is safe and effective as the legally marked predicate devices and that the PICOPLUS 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 PICOPLUS Laser System is substantially equivalent to the Cutera Enlighten III Laser System and the Quanta System S.P.A. Discovery Pico Family and can be legally marketed in the U.S.