February 4, 2022

Lutronic Corporation
Haewon Park
Regulatory Affairs Specialist
Lutronic Center, 219, Sowon-Ro
Deogyang-gu, Goyang-Si, Geonggi-do 410220
Korea, South

Re: K213569
Trade/Device Name: HOLLYWOOD SPECTRA 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 29, 2021
Received: November 9, 2021

Dear Haewon Park:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213569

Device Name
HOLLYWOOD SPECTRA Laser System

Indications for Use *(Describe)*

The HOLLYWOOD SPECTRA System is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatological and general surgical procedures for coagulation and hemostasis.

1064nm in nanosecond mode, including microbeam handpieces:
- Tattoo removal: dark ink (black, blue, and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of melasma

1064nm in Spectra (long-pulse) mode:
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):
- Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of Lentigines
- Treatment of Café-au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyperpigmentation
- Treatment of Becker's Nevi, Freckles, and Nevi spilus

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 (K213569)

Lutronic Corporation
HOLLYWOOD SPECTRA Laser System

I. SUBMITTER

Lutronic Corporation
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Deogyang-Gu, Goyang-Si,
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Republic of Korea

Contact Person
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Phone: 1-978-447-4763

Date Revised: January 31st, 2022

II. DEVICE

Trade Name:	HOLLYWOOD SPECTRA Laser System
Common or Usual Name:	Surgical Laser
Classification Name:	GEX – Powered Laser Surgical Instrument For Use in General and Plastic Surgery and Dermatology 21 C.F.R. 878.4810, Class II

III. PREDICATE DEVICES

1. Primary Predicate Device

Trade Name:	SPECTRA Laser System
Common or Usual Name:	Surgical Laser
Classification Name:	GEX – Powered Laser Surgical Instrument for use in General and Plastic Surgery and Dermatology 21 C.F.R. 878.4810, Class II
Premarket Notification:	Lutronic Corporation K113588 (2/2/2012)

2. Secondary Predicate Device

Trade Name:	Chrome
Common or Usual Name:	Surgical Laser
Classification Name:	GEX – Powered Laser Surgical Instrument for use in General and Plastic Surgery and Dermatology 21 C.F.R. 878.4810, Class II
Premarket Notification:	Quanta System SPA K202503 (11/18/2020)

3. Tertiary Predicate Device

Trade Name:	Fotona QX Nd:YAG/KTP Laser System Family
Common or Usual Name:	Nd:YAG/KTP Dermatology and Surgical Laser
Classification Name:	GEX – Powered Laser Surgical Instrument for use in General and Plastic Surgery and Dermatology 21 C.F.R. 878.4810, Class II
Premarket Notification:	Fotona d.o.o K083889 (4/23/2009)

IV. DEVICE DESCRIPTION

The HOLLYWOOD SPECTRA Laser System contains a Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) resonator which generates Q-switched and/or pulsed laser sources at the nominal wavelength of 1064 nm and 532 nm using KTP. The outputs of each laser generator and the aiming beam (655 nm) are delivered by articulated arm to a fixed (collimated), or focusing variable (zoom) spot handpiece, or a dual focused dots microbeam handpiece, or a 585nm/650nm dye laser converter handpiece. The dye handpieces convert the KTP 532 nm wavelength beam into a 585 nm or 650 nm wavelengths, correspondingly.

When the beam contacts human tissue, the energy in the beam is absorbed, resulting in a very rapid, highly localized temperature increase to the target chromophores such as melanin and tattoo particles. This increases localized temperature of the chromophores. The instantaneous temperature-increase causes fragmentation of the chromophores to smaller particles. By directing the beam onto specific tissue locations, using different handpieces, and controlling the treatment fluence, the intensity of the temperature of the target can be varied. The physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam.

The user activates laser emission by means of a footswitch. All handpieces are equipped with sensors for automatic detection of a handpiece type and the spot size. The HOLLYWOOD SPECTRA laser system is controlled via a touchscreen guided user interface in the front of the device.

V. INDICATIONS FOR USE

The HOLLYWOOD SPECTRA Laser System is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

1064nm in nanosecond mode, including microbeam handpieces:

- Tattoo removal: dark ink (black, blue, and brown)

- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of melasma

1064nm in Spectra (long-pulse) mode:

- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):

- Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of Lentigines
- Treatment of Café-au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyperpigmentation
- Treatment of Becker’s Nevi, Freckles, and Nevi spilus

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Lutronic Corporation believes that the HOLLYWOOD SPECTRA Laser System described in this notification and for use under the conditions of the proposed labeling is substantially equivalent to three legally marketed predicate devices that are Class II medical device. As shown in the Technical Characteristics Comparison (Table 1), the 1064 nm and 532 nm functions of the HOLLYWOOD SPECTRA Laser System are substantially equivalent to the 1064 nm and 532 nm functions of the Lutronic Corporation SPECTRA Laser System, Quanta Chrome, and Fotona QX Nd:YAG/KTP Laser System Family. As shown in Table 2, the microbeam handpiece's technological and performance characteristics of the HOLLYWOOD SPECTRA Laser System are substantially equivalent to those of the Quanta Chrome's standard microbeam handpiece.

Utilizing FDA's Guidance for Industry and FDA Staff "Format for traditional and Abbreviated 510(k)s", the proposed device, the HOLLYWOOD SPECTRA Laser System is substantially equivalent to the predicate device in terms of intended use, technological characteristics, and performance characteristics. The HOLLYWOOD SPECTRA Laser System is as safe, as effective, and performs as well as the predicate devices.

Table 1. Technical Characteristics Comparison

	This Submission HOLLYWOOD SPECTRA	Predicate 1 SPECTRA	Predicate 2 Chrome	Predicate 3 Fotona QX
510(k)	K213569	K113588	K202503	K083889
Applicant	**Lutronic**	**Lutronic**	**Quanta**	**Fotona d.o.o**
Product Code Classification Regulation Num	GEX Class II 21 CFR 878.4810	GEX Class II 21 CFR 878.4810	GEX Class II 21 CFR 878.4810	GEX Class II 21 CFR 878.4810
Laser Source Wavelength	Nd:YAG 1064nm, 532nm	Nd:YAG 1064nm, 532nm	Nd:YAG 1064nm, 532nm	Nd:YAG 1064nm, 532nm
Modes	QS Mode Q-PTP, Q-3, Q-4 Mode Spectra Mode (Long-pulse Mode) 532 Mode	QS Mode Spectra Mode (Long-pulse Mode) 532 Mode	QS Mode IPL Pulsed Mode	QS Mode Long-Pulse Mode
Pulse Duration	**1064 nm** 5-10 ns (QS, Q-PTP mode) 10-20 ns (Q-3, Q-4 mode) 0.3 ms (Long-pulse) **532 nm** 5-10 ns (Q-switched)	**1064 nm** 5-10 ns (QS) 0.3 ms (Long-pulse) **532 nm** 5-20 ns (Q-switched)	**1064 nm** 6 -12 ns (QS) 0.3-50 ms (Pulsed mode) **532 nm** 6 -12 ns (Q-switched) **IPL** Up to 40 ms (IPL)	**1064 nm** 5-20 ns (QS) 0.25 ms (Long pulse) **532 nm** 5-20 ns (Q-switched)
Max Energy	**1064 nm** Up to 1200 mJ (Q-switched) Up to 1500 mJ (Spectra) Up to 1400 mJ (Q-PTP, Q-3, Q-4) **532 nm** Up to 400 mJ (Q-switched)	**1064 nm** Up to 1200 mJ (Q-switched) Up to 1500 mJ (Spectra) **532 nm** Up to 600 mJ (Q-switched)	**1064nm** Up to 1600 mJ (Q-switched) Up to 15000 mJ (long pulsed) **532nm** Up to 800 mJ (Q-switched) **IPL** NA	**1064 nm** Up to 1600 mJ (Q-switched) Up to 5000 mJ (long pulsed) **532 nm** Up to 600 mJ (Q-switched)
Max. Fluence	**1064 nm** Up to 12 J/cm^2 **532 nm** Up to 6.3 J/cm^2	**1064 nm** Up to 12 J/cm^2 **532 nm** Up to 6.3 J/cm^2	**1064 nm** Up to 48 J/cm^2 (Q-switched) Up to 300 J/cm^2 (pulsed mode) **532 nm** Up to 15 J/cm^2 (Q-switched) **IPL** Up to 25 J/cm^2	Up to 12.7 J/cm^2

Spot Size	**1064 nm** Zoom handpiece 1 to 7 mm (Q-Switch, Spectra) 2 to 7 mm (Q-PTP, Q-3, Q-4) 8mm-Zoom-Collimated 3, 4, 5, 6, 7, 8 mm **532 nm** Zoom handpiece 0.8 to 6.0 mm diameter 8mm-Zoom-Collimated 2.6, 3.4, 4.3, 5.2, 6.0, 6.9 mm	**1064 nm** Zoom handpiece 1 to 7 mm (Q-Switch, Spectra) 8mm-Zoom-Collimated 3, 4, 5, 6, 7, 8 mm **532 nm** Zoom handpiece 0.8 to 6.0 mm diameter 8mm-Zoom-Collimated 2.6, 3.4, 4.3, 5.2, 6.0, 6.9 mm	**1064 nm** 2 to 8 mm diameter 2x2, 3x3, 4x4, 5x5, 7x7 mm^2 **532 nm** 3 to 10.5 mm diameter	**1064, 532 nm** 2 to 8 mm diameter
Repetition Rate	**1064, 532 nm** Up to 10 Hz **585nm** S1, 1, 2, 5 Hz **650nm** S1, 1, 2 Hz	**1064, 532 nm** Up to 10 Hz	**1064, 532 nm** Up to 20 Hz	**1064, 532 nm** Up to 10 Hz
Delivery	Articulated arm	Articulated arm	Articulated arm	Articulated arm

Table 2. Technological Characteristics Comparison for the Microbeam Handpiece

	This Submission HOLLYWOOD SPECTRA	**Predicate 1 SPECTRA**	**Predicate 2 Chrome**	**Predicate 3 Fotona QX**
510(k)	K213569	K113588	K202503	K083889
Applicant	**Lutronic**	**Lutronic**	**Quanta**	**Fotona d.o.o**
Microbeam Handpiece	**Present**	**Absent**	**Present**	**Absent**
Microbeam Handpiece Fluence per dot	**1064 nm** 1.09 ~40.63 J/cm^2 **532 nm** 0.16 ~ 16.40 J/cm^2	NA	**1064nm** 0.03~44.4 J/cm^2 (Standard) 0.2 ~16.5 J/cm^2 (High Coverage) **532 nm** 0.3~14.9 J/cm^2 (Standard) 0.05~5.95 J/cm^2 (High Coverage)	NA
Microbeam Handpiece Spot Size	**1064 nm** 8mm **532 nm** 6.9mm	NA	**1064, 532 nm** 8 mm (Standard) 9 mm (High Coverage)	NA
Microbeam Handpiece Peak Power per dot**	0.28 GW **(1064 nm)** 0.08 GW **(532 nm)**	NA	0.3 GW **(1064 nm)** 0.083 GW **(532 nm)**	NA

** Mathematically derived values

Table3. Indications for Use Statement Comparison

	This Submission HOLLYWOOD SPECTRA	Predicate 1 SPECTRA	Predicate 2 Chrome	Predicate 3 Fotona QX
510(k)	K213569	K113588	K202503	K083889
Applicant	**Lutronic**	**Lutronic**	**Quanta**	**Fotona d.o.o**
Indication For Use	The Hollywood Spectra System is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. **1064nm in nanosecond mode, including microbeam handpieces:** -Tattoo removal: dark ink (black, blue, and brown) -Removal of Nevus of Ota -Removal or lightening of unwanted hair with or without adjuvant preparation -Treatment of Common Nevi -Skin resurfacing procedures for the treatment of acne scars and wrinkles -Treatment of melasma **1064nm in Spectra (long-pulse) mode:** -Treatment of wrinkles -Treatment of mild to moderate inflammatory acne vulgaris **532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):** - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions	The SPECTRA Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. **532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):** - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Treatment of lentigines - Treatment of Café-au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyperpigmentation - Treatment of Becker's Nevi, Freckles, and Nevi Spilus **1064 nm Wavelength:** - Tattoo removal: dark ink (black, blue and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation - Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of melasma	Quanta Chrome (K202503) is cleared for the treatment of benign vascular lesions, benign pigmented lesions, and for hair, tattoo removal and the incision, excision, ablation, vaporization of soft tissue for General dermatology such as, but not limited to treatment of: **532 nm (Q-Switched, nanosecond mode), including microbeam handpieces:** Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos Treatment of benign vascular lesions including, but not limited to: - port wine birthmarks - telangiectasias - spider angioma - Cherry angioma - Spider nevi Treatment of benign pigmented lesions including, but not limited to: - cafe-au-lait birthmarks - Ephalides, solar lentigines - senile lentigines - Becker's nevi - freckles - common nevi - nevus spilus - Ota Nevus Treatment of seborrheic keratosis Treatment of post inflammatory hyperpigmentation Skin resurfacing procedures for the treatment of acne scars and wrinkles. **1064 nm (Q-Switched, nanosecond mode), including microbeam handpieces:** Removal of dark ink (black, blue and brown) tattoos Removal of benign pigmented lesions including; - nevus of Ota	**1064 nm wavelength in Q-switched mode**: - Removal of dark ink (black, blue, and brown) tattoos - Treatment of nevus of Ota - Treatment of common nevi - Removal or lightening of unwanted hair - Skin resurfacing procedures for the treatment of acne scars and wrinkles **1064 nm wavelength in non-Q-switched mode:** - Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for 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 - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris

	- Removal of Minor Vascular Lesions including but not limited to telangiectasias - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of Lentigines - Treatment of Café-au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyperpigmentation - Treatment of Becker's Nevi, Freckles, and Nevi spilus		- Café au lait spot - Ephalides, solar lentigo (lentigines) - Becker Nevus - Nevus spilus Treatment of common nevi Removal or lightening of unwanted hair Skin resurfacing procedures for the treatment of acne scars and wrinkles **1064 nm (pulsed) Dermatology/Plastic Surgery:** Intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of 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, keratosis and plaques. The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. The laser is also indicated for the treatment of facial wrinkles. Additionally, the laser is indicated for the treatment of pseudofolliculitis barbae (PFB) and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as 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. It is indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. The laser is also indicated for benign pigmented lesions to reduce lesion size, for patients with benign lesions that would potentiallybenefit from aggressive treatment, and for patients with benign lesions that have not responded to other laser treatments. It is indicated for use on all skin types (Fitzpatrick I-VI) including tanned skin, and the removal and permanent	**532 un wavelength in Q-switched mode (nominal delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces)**: - Removal of light ink (red, sky blue, green, tan, purple, and orange) tattoos - Treatment of vascular lesions including, but not limited to: - port wine birthmarks - telangiectasias - spider angioma - cherry angioma - spider nevi

			reduction of unwanted hair in Fitzpatrick I-VI, including suntanned skin types. **IPL 590-1200nm; 625-1200nm; 650-1200nm** Indicated for permanent hair removal. 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 **IPL 550-1200nm; 570-1200nm** Indicated for photocoagulation of dermatological benign vascular lesion (i.e. face telangiectasia), photothermolysis of blood vessels (treatment of facial and leg veins), and treatment of benign pigmented lesions. **IPL 400-1200nm** Indicated for inflammatory acne (mild to moderate acne vulgaris). **Integrated Skin Cooler** The intended use of the integrated cooling system in the laser hand piece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluencies for laser treatments such as hair removal and benign vascular lesion, and to reduce the potential side effects of laser treatments.	

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The tip of handpiece is considered tissue-contacting component for a duration of less than 24 hours and its chemical formulation is Aluminum (Max. 96%, CAS No. 7429-90-S). The contact type of the HOLLYWOOD SPECTRA Laser System is as follows: surface device, intact skin, limited duration.

The biocompatibility evaluation for the HOLLYWOOD SPECTRA Laser System was conducted in accordance with the FDA's Guidance for Industry and FDA Staff "Use of International Standard 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" as recognized by FDA. The handpiece tip testing included the following tests:

- Cytotoxicity
- Dermal Sensitization
- Intracutaneous Irritation

Sterilization and Shelf-Life

The HOLLYWOOD SPECTRA Laser System is not provided sterile and does not need to be sterilized. The handpiece and the body are cleaned with a soft cloth moistened with isopropyl alcohol or ethanol of 90% strength or higher. The HOLLYWOOD SPECTRA Laser System is reusable and does not have a restricted shelf-life. The expected service life is about 5 years.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the HOLLYWOOD SPECTRA Laser System, consisting of the system main body, articulated arm, handpieces, and footswitch. The system complies with the following standards for safety and EMC.

- IEC 60601-1:2012, ed 3.1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2 Edition 4: 2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
- IEC 60601-2-22: 2012-10 ed 3.1, Medical Electrical Equipment - Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment

- IEC 60825-1 Ed. 3.0 (2014) Safety of laser products – Part 1: Equipment classification and requirements

Software Verification and Validation Testing

Software verification and validation testing were conducted, and 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 "moderate" level of concern since a failure of the software could result in minor injury to a patient or to a user of the device.

Performance Bench Testing

Test was performed to ensure that the HOLLYWOOD SPECTRA Laser System performs as intended and documentation was provided. Testing included laser pulse width, laser pulse repetition rate, laser pulse energy, laser beam spectrum and bandwidth, laser beam spot size, and flash lamp lifetime.

VIII. CONCLUSIONS

The HOLLYWOOD SPECTRA Laser System has the same intended use, similar indications for use, and the same fundamental scientific technology as its predicates. The technology and performance specifications of the subject device are equivalent to its identified predicate devices and therefore do not present any new concerns of safety and effectiveness. Therefore, the HOLLYWOOD SPECTRA Laser System is as safe, as effective, and performs as well as the legally marketed predicate devices.