LUVO Medical Technologies, Inc.
Mr. Gregory Berzak
Regulatory Affairs Officer
125 Fleming Dr
Cambridge, N1T 2B8 Ca

Re: K193072
Trade/Device Name: Lucent : IPL
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: ONF
Dated: October 28, 2019
Received: November 4, 2019

Dear Gregory Berzak:

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,

Jessica Mavadia-Shukla
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K193072

Device Name

Lucent : IPL

Indications for Use *(Describe)*
The Lucent : IPL is Intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general
and plastic surgery, and dermatology.

Indication for Use for the 430-980nm wavelength

• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae.
• Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, angiomas and spider angiomas, and poikiloderma of Civatte.
• For use on Fitzpatrick skin types (I-V)

Indication for use for the 515-980nm wavelength

• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae.
• Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, angiomas and spider angiomas, poikiloderma of Civatte and Lentigines.
• For use on Fitzpatrick skin types (I-V)

Indication for use for the 560-980nm wavelength

• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae.
• Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, angiomas and spider angiomas, poikiloderma of Civatte and Lentigines.
• The removal of unwanted hair to effect stable long-term or permanent hair reduction
• For use on Fitzpatrick skin types (I-V)

Indication for use for the 585-980nm wavelength

• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae.
• Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, angiomas and spider angiomas, and poikiloderma of Civatte.
• The removal of unwanted hair to effect stable long-term or permanent hair reduction
• For use on Fitzpatrick skin types (I-V)

Indication for use for the 640-980nm wavelength

• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae.
• Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, angiomas and spider angiomas, and poikiloderma of Civatte.
• The removal of unwanted hair to effect stable long-term or permanent hair reduction
• For use on Fitzpatrick skin types (I-V)

Indication for use for the 700-980nm wavelength

• The removal of unwanted hair and to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regime
• For use on Fitzpatrick skin types (I-V)

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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K193072
510(K) Summary
Lucent : IPL System

This 510(K) Summary of safety and effectiveness for the Lucent : IPL is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	LUVO Medical Technologies, Inc.
Address:	LUVO Medical Technologies, Inc. 125 Fleming Dr Cambridge, Ontario, Canada N1T 2B8
Contact Person:	Mr. Gregory Berzak
Telephone:	519-6203900– phone gregoryb@clarionmedical.com
Preparation Date:	October 15, 2019
Device Trade Name:	Lucent : IPL
Common Name:	Powered light based non-laser surgical instrument with thermal effect
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and dermatology
Regulation Number:	21 CFR 878.4810 (Product Code: ONF)
Legally Marketed Predicate Devices:	Primary Predicate : Alma Harmony XL Multi-Application Platform / Secondary Predicate: Lumenis M22 System
510(K) number:	K072564/ K142860
Regulatory Class:	Class II Prescription Use
Description of the Lucent : IPL:	The LUVO Medical Technologies, Inc. Lucent : IPL isa multi-wavelength non-invasive system for IPL skin treatments, treatment of vascular and pigmented lesions, and hair removal using multiple filters reflecting a wavelength range of 430nm to 980nm. The Lucent : IPL system consists of a system console, electronics and software, cooling system, and handpiece with six filters
Intended use of Lucent : IPL:	The Lucent : IPL is intended for use in dermatologicand general surgical procedures. See the below Indications for Use Comparison Table.
Performance Data:	The following performance data was provided in support of

the substantial equivalence determination:

ES60601-1:2005/(R)2012 and A1:2012 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance;

IEC 60601-1-2 Edition 4.0 2014-02 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility

IEC 60601-2-57 Edition 1.0 2011-01 Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

Results of Clinical Study:

A human clinical study was not required as the device is substantially equivalent to the predicate devices.

Technical Specifications / Indications for Use Comparison:

	510(K) Submission **Lucent : IPL (K193072)**	**Predicate** **K142860 – Lumenis M22 System**
Characteristic		
Wavelength (nm)	**430-980nm**	**400-1200nm**
Intended Use	Intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology

Indications for Use	• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae. • Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, angiomas and spider angiomas, and poikiloderma of Civatte. • For use on Fitzpatrick skin types (I-V)	• Mild to Moderate inflammatory (Acne Vulgaris) Benign epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles) and tattoos • Cutaneous lesions, including warts, scars and striae • Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, • Erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations • Removal of unwanted hair from all skin types, and to effect stable long term, or permanent* hair reduction in skin types • I-V through selective targeting of melanin in hair follicles
Pulse Width (msec)	3-35	4-20
Energy Density (Fluence) (J/cm^2)	6-40	10-35
Spot Size (mm)	15mm x 40mm	15mm x 35mm / 8mm x 15mm

	510(K) Submission **Lucent : IPL (K193072)**	**Predicate** **K072564 – Alma VL515 IPL handpiece**
Characteristic		
Wavelength (nm)	**515-980nm**	**515nm-950nm**
Intended Use	Intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology

Indications for Use	• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae. • Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, angiomas and spider angiomas, poikiloderma of Civatte and Lentigines • For use on Fitzpatrick skin types (I-V)	• Moderate inflammatory acne (acne vulgaris) • Tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars ,striae; dyschromia, hyperpigmentation, melasma, epithelides (freckles), lentigines, nevi, and café-au-lait macules • Benign cutaneous vascular lesions, including port wine stains,hemangiomas, facial, truncal and legtelangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations • For use on skin types(I-V)
Pulse Width (msec)	3-35	10-15
Energy Density (Fluence) (J/cm2)	6-40	10-30
Spot Size (mm)	15mm x 40mm	3cm^2 and 6.4 cm^2

	510(K) Submission **Lucent : IPL (K193072)**	**Predicate** **K072564 – Alma IPL handpiece VL/PL, VP and SSR**
Characteristic		
Wavelength	**560-980nm**	**540-950nm**
Intended Use	Intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology

Indications for Use	• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae. • Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias,angiomas and spider angiomas, poikiloderma of Civatte and Lentigines • The removal of unwanted hair to effect stable long-term or permanent hair reduction • For use on Fitzpatrick skin types (I-V)	• The treatment of moderate inflammatory acne vulgaris.· • The treatment of benign pigmented epidermal lesions includingdyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and caf6-au-lait macules. • The treatment of cutaneous lesionsincluding warts, scars and striae. · • The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncaland leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • The removal of unwanted hair to effectstable long-term or permanent hair reduction. • Use on all skin types (FitzpatrickI-VI).
Pulse Width (msec)	3-35	10-15
Energy Density (Fluence) (J/cm2)	6-40	1-15 and 10-30
Spot Size (mm)	15mm x 40mm	3 cm^2

	510(K) Submission **Lucent : IPL (K193072)**	**Predicate K072564 – Alma SR IPL handpiece**
Characteristic		
Wavelength (nm)	**585-980nm**	**570-950nm**
Intended Use	Intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology

Indications for Use	• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae. • Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, angiomas and spider angiomas, and poikiloderma of Civatte. • The removal of unwanted hair to effect stable long-term or permanent hair reduction. • For use on Fitzpatrick skin types (I-V)	• The treatment of moderate inflammatory acne vulgaris. • The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles). • The treatment of face and body vascular and pigmented lesions. • The treatment of cutaneous lesions, including scars and striae. • The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • The removal of unwanted hair to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI).
Pulse Width (msec)	3-35	10-15
Energy Density (Fluence) (J/cm2)	6-40	10-25
Spot Size (mm)	15mm x 40mm	6.4 cm^2

	510(K) Submission **Lucent : IPL (K193072)**	**Predicate** **K072564 – Alma HR Module AFT Handpiece**
Characteristic		
Wavelength (nm)	**640-980nm**	**650-950nm**
Intended Use	Intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology

Indications for Use	• Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides (freckles), and striae. • Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial and truncal telangiectasias, angiomas and spider angiomas, and poikiloderma of Civatte. • The removal of unwanted hair to effect stable long-term or permanent hair reduction. • For use on Fitzpatrick skin types (I-V)	• The treatment of moderate inflammatory acne vulgaris. • The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles). • The treatment of face and body vascular and pigmented lesions. • The treatment of cutaneous lesions, including scars and striae. • The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • The removal of unwanted hair to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI)
Pulse Width (msec)	3-35	30-50
Energy Density (Fluence) (J/cm2)	6-40	5-25
Spot Size (mm)	15mm x 40mm	6.4 cm^2

	510(K) Submission **Lucent : IPL (K193072)**	**Predicate** **K072564 - Alma SHR IPL**
Characteristic		
Wavelength (nm)	**700-980nm**	**780-950nm**
Intended Use	Intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology

Indications for Use	• The removal of unwanted hair and to effect stable long-term or permanent hair reduction. Permanent reduction in hair regrowth 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 • Use on skin types (Fitzpatrick I-V)	• The treatment of pseudofolliculitis barbae(PFB). • The removal of unwanted hair and to effect stable long-term or permnanent hair reduction. • Use on all skin types (Fitzpatrick I-VI), including tannedskin.	
Pulse Width (msec)	3-35	≤30msec/1,3 and 30 sec	≤6msec
Energy Density (Fluence) (J/cm2)	6-40	1-7 and 0.5-1.5	1-7
Spot Size (mm)	15mm x 40mm	3 cm^2	6.4 cm^2

Conclusion: The Lucent : IPL's intended use, indications for use and technical specifications are substantially equivalent to the Harmony XL Multi-Application Platform and the M22 System.