July 14, 2021

Gregory Berzak
Director of Regulatory Affairs and Quality Compliance
125 Fleming Drive
Cambridge, Ontario N1T 2B8
Canada

Re: K203728
Trade/Device Name: Darwin
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, GEX
Dated: June 10, 2021
Received: June 15, 2021

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,

Long Chen, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203728

Device Name

Darwin

Indications for Use *(Describe)*

The Diode Laser Handpiece is indicated for:

The hair removal single (HRS) and hair removal moving (HRM) mode are intended for permanent reduction in hair regrowth defined as 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 regimen. Use on all skin types (Fitzpatrick I-VI) including tanned skin

The IPL Handpieces are indicated for:

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.

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

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)

The RF MicroNeedling Handpiece is indicated for:

Use in dermatologic and general surgical procedures for electro-coagulation and hemostasis

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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K203728 - Summary

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

I. **510(K) Submitter**

a) Company Name and Address:

LUVO Medical Technologies, Inc.
125 Fleming Dr
Cambridge, Ontario, N1T 2B8
Canada

b) Company Contact:

Mr. Gregory Berzak
Director of Regulatory Affairs and Quality Compliance
Phone: 519-620-3900
Email: gregoryb@clarionmedical.com

c) Preparation Date: January 11, 2021

II. DEVICE

Device Trade Name: Darwin

Common Name: Powered laser surgical instrument Radio Frequency generator

Regulation Name: 21 CFR 878.4810, Laser Surgical Instrument for use in general and plastic surgery and in dermatology

21 CFR 878.4400, Electrical cutting and coagulation device and accessories; Massager, Vacuum, Radio Frequency Induced Heat

Product Codes: GEX, GEI

Regulatory Class: Class II Prescription Use

III. Predicate Device

Legally marketed Predicate Devices:

Device Name	510K number	Product Code
Bare: 808	K193446	GEX
Lucent IPL	K193072	GEX
Potenza	K192545	GEI

IV. Device Description

The Darwin is a Class II Medical Device that combines multiple technologies into one platform for use in dermatologic and aesthetic procedures. The system is comprised of a micro-processor-controlled and user-friendly console that houses the power supply, the electronics, and the user interface. It then has 3 handpieces that are attached to the console, and through the user interface can be selected for use in the treatments.

There are 3 separate handpieces. Each handpiece has its own indication for use.

- Diode Laser Handpiece
- IPL Handpiece
- RF Microneedling Handpiece

The Diode Laser handpiece uses laser light in the 808nm wavelength for hair removal. The laser eliminates hair, employing a method knows as selective photothermolysis. This involves disabling hair regrowth mechanism by raising the temperature of the hair follicle high enough to irreversibly damage the follicle's germinative cells without damaging the epidermis and the surrounding tissue. The germinative root resides inside the follicle but is located to the outer follicles sheath. Therefore, the complete follicle volume must be heated above 70° C to accomplish permanent destruction of all stem cell.
Delivering a pulsed light using a coherent light source of 808nm wavelength, the diode laser handpiece is intended for hair removal and permanent hair reduction on skin types (Fitzpatrick skin types I - V). The user can choose from two modes: hair removal shot (HRS) and hair removal moving (HRM) when using the Diode laser handpiece.

Specific indications for each wavelength are discussed in the tables below.

The **IPL Handpiece** produces light pulses with a specific duration, intensity, and spectral distribution allowing for a controlled and confined energy delivery into tissue. IPL use in dermatology relies on the basis that certain targets for energy

absorption (chromophores) are capable of absorbing energy from this broad spectrum of light wavelength (absorptive band) without exclusively being targeted by their highest absorption peak.

The IPL Handpiece has various filters to create different wavelengths. The handpiece is 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. Each wavelength has its own indications for use, which are listed in the tables below.

Filters for the non-invasive IPL handpiece include 430nm, 515nm, 560nm, 585, 640nm, and 700nm. The user can select two treatment modes: ST (Skin Type) and HR (Hair Removal) when using the IPL handpiece.

The Needle RF handpiece operates using sterile, single-use, multi-needle tips (10 pin and 25 pin) and is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis. The RF Microneedling handpiece generates radiofrequency (RF) energy by means of bipolar RF at 2 MHz.

The RF handpieces penetrates micro needles directly into the skin and delivers high frequency energy. This energy flows through the electrode to the tissue and uses heat generated by load or contact resistance to induce coagulation. The RF energy is delivered through the skin into the target tissue via a handpiece equipped with an electrode tip. As the RF energy passes through the tissue, it generates an electrothermal reaction which is capable of coagulating the tissue.

The RF Microneedling Handpiece has a single use sterile disposable cartridge. This is the only sterile component on the device. No handpieces or accessories are intended to be sterilized or disinfect by the end user. There are no components of the Darwin that are reusable.

V. Indications for Use

The device is intended for use in dermatologic and general surgical procedures.
The Diode Laser handpiece is indicated for:

- The hair removal single (HRS) and hair removal moving (HRM) mode are intended for permanent reduction in hair regrowth defined as 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 regimen. Use on all skin types (Fitzpatrick I-VI) including tanned skin

The IPL Handpiece is indicated for:

- 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.

- 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

- 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)

The RF MicroNeedling Handpiece is indicated for:

- Use in dermatologic and general surgical procedures for electro-coagulation and hemostasis

VI. Comparison of Technological Characteristics with the Predicate device

Comparison for the Darwin characteristics to the predicate device is included below and separated based on each handpiece technology and indication for use.

- **Darwin Diode Laser Handpiece**

	Darwin Diode Laser Handpiece	**Bare: 808 K193466**	**Comparison**
Indication for Use	The hair removal single (HRS) and hair removal moving (HRM) mode are intended for permanent reduction in hair regrowth defined as 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 regimen. Use on all skin types (Fitzpatrick I-VI) including tanned skin	The hair removal single (HRS) and hair removal moving (HRM) mode are intended for permanent reduction in hair regrowth defined as 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 regimen. Use on all skin types (Fitzpatrick I-VI) including tanned skin	Same

Technical Comparison	**Darwin Diode Laser Handpiece**		**Bare: 808 K193466**		**Comparison**
Wavelength	808		808		Same
Laser Media	Solid State		Solid State		Same
Modes	HRS	HRM	HRS	HRM	Same
Energy Density (Fluence)	2-120J/cm^2	2-20J/cm^2	2-120J/cm^2	2-20J/cm^2	Same
Spot Size (mm)	14 x 14	14 x 14	14 x 14	14 x 14	Same
Pulse Width (msec)	15-400	15-266	15-400	15-266	Same
Repetition Rate (Hz)	3-10		3-10		Same

- **Darwin IPL Handpiece**

	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
Indication for Use	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. 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,	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. 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,	Same

	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
	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, 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,	

	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
	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 Indication for use for the 640-980nm wavelength • Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides	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 Indication for use for the 640-980nm wavelength • Benign pigmented epidermal and cutaneous lesions including dyschromia, hyperpigmentation, melasma, Ephelides	

	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
	(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)	(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)	

- **Technical Comparison by Wavelength for the IPL Handpiece**

	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
Wavelength(nm)	430-980nm	430-980nm	Same
Pulse Width (msec)	3-35	3-35	Same
Energy Density (Fluence J/cm^2	6-40	6-40	Same
Spot Size	15mm x 40mm	15mm x 40mm	Same
	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
Wavelength(nm)	515-980nm	515-980nm	Same
Pulse Width (msec)	3-35	3-35	Same
Energy Density (Fluence J/cm^2	6-40	6-40	Same
Spot Size	15mm x 40mm	15mm x 40mm	Same
	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
Wavelength(nm)	560-980nm	560-980nm	Same
Pulse Width (msec)	3-35	3-35	Same
Energy Density (Fluence J/cm^2	6-40	6-40	Same
Spot Size	15mm x 40mm	15mm x 40mm	Same
	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
Wavelength(nm)	585 - 980	585 - 980	Same
Pulse Width (msec)	3-35	3-35	Same

Energy Density (Fluence J/cm^2	6-40	6-40	Same
Spot Size	15mm x 40mm	15mm x 40mm	Same
	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
Wavelength(nm)	640-980	640-980nm	Same
Pulse Width (msec)	3-35	3-35	Same
Energy Density (Fluence J/cm^2	6-40	6-40	Same
Spot Size	15mm x 40mm	15mm x 40mm	Same

	Darwin IPL Handpiece	**Lucent: IPL K193072**	**Comparison**
Wavelength(nm)	700-980	700-980	Same
Pulse Width (msec)	3-35	3-35	Same
Energy Density (Fluence J/cm^2	6-40	6-40	Same
Spot Size	15mm x 40mm	15mm x 40mm	Same

- **Comparison of the RF Microneedling Handpiece**

	Darwin RF Microneedling Handpiece	**Potenza K192545**	**Comparison**
Indication for Use	Use in dermatologic and general surgical procedures for electro-coagulation and hemostasis	Use in dermatologic and general surgical procedures for electro-coagulation and hemostasis	Same
Technical comparison			
Output Frequency	2MHz	1MHz and and 2MHz	Similar

Maximum power delivered to patient	Up to 36W	Up to 50W (step :1 Watt) 200 ohm	Similar
Impedance	200 ohm	200 ohm	
Treatment Temperature Range	40°C to 44°C	39°C to 42°C	Similar
Treatment Levels	1-10 levels (1=low, 10= high)	1-10 levels (1=low, 10= high)	Same
Power Source	AC 220-240 V, 50 /60 Hz, 16A	100V-240V 50/60 Hz, 500VA	Similar
Active Accessory			
Type	Microneedle	Microneedle	Same
Operating Mode	BiPolar	BiPolar	Same
Pin Configuration	10 and 25 pin	21 and 49 Pin	Similar
Treatment Area	10pin: 2*8mm 25pin: 8*8mm	Spot Size (Treated Area): 1cm x 1cm	Similar
Material	Tip: Polycarbonate Needles: SU304	Tip: Polycarbonate Needles: SU304	Same
Single Use / Reusable	Single Use	Single Use	Same
Method of Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same
Depth of Skin Ablation	0.5 – 3.5mm	0.5-4.0mm	Similar

VII. Performance Data

The following performance data was provided in support of the substantial equivalence determination:

- IEC 60601-1 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance.
- IEC 60601-1-2 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility
- IEC 60601-2-22 Test for Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60601-2-2 Test for Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

RF Microneedling handpiece Thermal testing to support substantial equivalence:

The Darwin System microneedling RF device equipped with cartridges containing 2x5 and 5x5 needle arrays demonstrated consistent formation of measurable thermal lesions for medium and highest energy level settings in the treatment of in vivo pig skin and in vitro liver and kidney tissues at a temperature close to physiological. It can be concluded that treatment by this device at the appropriate testing settings will result in a desirable clinical treatment effect.

The fact that study was performed in vivo model strongly supports this conclusion.

VIII. Conclusions

The Darwin has the same technology, principle of operation, indications for Use, and technical specifications as the predicate device. Performance test results also demonstrated the subject device can perform the same intended use as safely and effectively as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.