November 15, 2021

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

Re: K212607
Trade/Device Name: Darwin
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, GEI
Dated: August 12, 2021
Received: August 17, 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 and Part 809; 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

Indications for Use

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

510(k) Number *(if known)*
K212607

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 Handpiece has various filters to create different wavelengths. The various wavelengths are broken down by wavelength and applicable 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.

The IPL handpiece is indicated for:

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)

RF Microneedling Handpiece

The RF MicroNeedling Handpiece is indicated for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis

Thermal RF Handpiece

The Thermal RF Handpiece is indicated for heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

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)

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510K Summary
Darwin System
K212607

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.

Applicant:	LUVO Medical Technologies, Inc.
Address:	LUVO Medical Technologies, Inc. 125 Fleming Dr Cambridge, Ontario, Canada N1T 2B8
Contact Person:	Mr. Gregory Berzak
Telephone:	519-620-3900– phone gregoryb@clarionmedical.com
Preparation Date:	November 11, 2021
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

Legally Marketed Predicate Devices:

Device Name	510K number	Product Code
Darwin	K203728	GEX, GEI
RF Thermal System	K210129	GEI
Spirit Hair Removal Laser (Reference Device)	K153718	GEX

Regulatory Class:	Class II Prescription Use
Description of the Darwin Laser System:	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 has 4 handpieces that are attached to the console, which can be selected for use in treatment through the user interface. There are 4 separate handpieces. Each handpiece has its own indication for use. • Diode Laser Handpiece • IPL Handpiece • RF Microneedling Handpiece • Thermal RF **The Diode Laser handpiece** uses laser light in the 808nm wavelength for hair removal. The laser removes hair, employing a method knows as selective photothermolysis. This involves raising the temperature of the hair follicle without damaging the epidermis and the surrounding tissue. Delivering 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. 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 RF Microneedling 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 handpiece 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. The RF Microneedling

	handpieces are not intended to be sterilized or disinfected by the end user. **The Thermal RF Handpiece** is indicated for heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.
Intended use of Darwin	The device is intended for use in dermatologic and general surgical procedures. See a full list of indications for use for each handpiece in the tables below.

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 ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process

Comparison for the Diode Laser Handpiece

	Subject Device		Predicate Device		
	Darwin Diode Laser Handpiece		Darwin Diode Laser Handpiece (K203728)		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					
Wavelength	808		808		Same
Laser Media	Solid State		Solid State		Same
Modes	HRS	HRM	HRS	HRM	Same
Energy Density (Fluence)	5-60 J/cm^2	5-30J/cm^2	1-120 J.cm^2	2-20J/cm^2	Similar. See Reference Device comparison below
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

Comparison of Diode Laser Handpiece with Reference Device

	Subject Device		Reference Device		
	Darwin Diode Laser Handpiece		Spirit Hair Removal Laser(K153718)		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 Spirit Hair Removal laser Family is generally intended for dermatological use. The devices are specifically indicated for hair removal, permanent hair reduction by using selective laser energy. The Spirit Hair Removal laser Family is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin. Permanent reduction in hair regrowth is defined as the longterm, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.		Same.
Technical Comparison					
Wavelength	808		810		Same
Laser Media	Solid State		Solid State		Same
Modes	HRS	HRM	N/A	N/A	Same
Energy Density (Fluence)	5-60 J/cm^2	5-30J/cm^2	6-90J/cm^2 max		The Darwin Diode fluence is a subset of the Spirit.
Spot Size (mm)	14 x 14	14 x 14	12 x 16		Nearly Identical
Pulse Width (msec)	15-400	15-266	Up to 310ms		Nearly Identical

Repetition Rate (Hz)	3-10	<10Hz	Same

Comparison of Darwin IPL Handpiece with Predicate Device

	Darwin IPL Handpiece	Darwin PL Handpiece Predicate	
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, 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,	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	Same

	Darwin IPL Handpiece	Darwin PL Handpiece Predicate	
	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	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,	

	Darwin IPL Handpiece	Darwin PL Handpiece Predicate	
	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)	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	

	Darwin IPL Handpiece	Darwin PL Handpiece Predicate	
		completion of a treatment regime • For use on Fitzpatrick skin types (I-V)	

Technical Comparison by Wavelength for the IPL Handpiece

	Darwin IPL Handpiece	Darwin IPL Handpiece Predicate	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	Darwin IPL Handpiece Predicate	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	Darwin IPL Handpiece Predicate	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	Darwin IPL Handpiece Predicate	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	Darwin IPL Handpiece Predicate	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	Darwin IPL Handpiece Predicate	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 with Predicate

	Darwin RF Microneedling Handpiece	Darwin RF Microneedling Handpiece Predicate	
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	2MHz	Same
Maximum power delivered to patient	Up to 36W	Up to 36W	Same
Impedance	200 ohms	200 ohms	
Treatment Temperature Range	40°C to 44°C	40°C to 44°C	Same
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	AC 220-240 V, 50 /60 Hz, 16A	Same
Active Accessory			
Type	Microneedle	Microneedle	Same
Operating Mode	BiPolar	BiPolar	Same
Pin Configuration	10 and 25 pin	10 and 25 pin	Same
Treatment Area	10pin: 2*8mm 25pin: 8*8mm	10pin: 2*8mm 25pin: 8*8mm	Same
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 – 3.5mm	Same

Comparison of Thermal RF Handpiece to Predicate Device

	Thermal RF Handpiece	Thermal RF Handpiece Predicate K210129	
Indication for Use	Heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation	Heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation	Same
Technical Specification			
Frequency (MHz)	4	4	Same
Operation Type	Monopolar	Monopolar	Same
Output Power	Up to 60W	Up to 60W	Same
TRF-E Tip			
Treatment Area	0.38 cm^2	0.38 cm^2	Same
TRF-R Tip			
Treatment Area	2.54 cm^2	2.54 cm^2	Same
TRF-S tip			
Treatment Area	3.61 cm^2	3.61 cm^2	Same

Conclusion: The current Darwin submission has the same technology, principle of operation and indications for use as the predicate devices (K203728 and K210129).

The minor differences in fluence and pulse width from the reference device (K153718) do not affect the safety and efficacy of the Darwin. The Darwin System is substantially equivalent to the predicate devices.