Section 5 510(k) summary

I Submitter

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II Device

Trade Name of Device: Diode Laser Treatment System
Models: KM200D, KM300D, KM600D, KM800D, KM900D
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery

III Predicate Devices

Trade Name of Device: Diode Laser Therapy Machine
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery
510(k) number: K161692

Trade Name of Device: Diode Laser Hair Removal System
Common name: Powered Laser Surgical Instrument
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product code: GEX
Review Panel: General & Plastic Surgery
510(k) number: K141973

IV Device description

The Diode Laser Treatment System consists of the main unit and a hand piece. The system uses a diode laser as an active medium placed in an optical cavity to produce amplified beam at the wavelength of 808 nm. A microprocessor is used to control electronics for the front panel. A self-contained water cooling system is built into the power supply unit.

The device provides 36 working modes, which are six modes for men and six modes for women. The men or women mode includes face, armpit, arm, body, bikini, leg mode respectively for different treatment part. The diode laser operates in a pulsed mode with a fixed pulse width and fixed pulse duration of the pulse train for each mode. The number of pulses can be adjusted within the preset range.

V Indications for use

The Diode Laser Treatment System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.

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.

VI Comparison of technological characteristics with the predicate devices

The Diode Laser Treatment System has the same technological characteristics and fundamental design as the predicate device. The subject device and the predicate devices are all designed for hair removal on different parts of the body. The differences between the subject device and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	**Diode Laser Treatment System (subject device)**	**Diode Laser Therapy Machine FG 2000-B K161692**	**Diode Laser Hair Removal System K141973**
Product code	GEX	GEX	GEX
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Indications for use	The Diode Laser Treatment System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin	The Diode Laser Therapy Machine is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin	The Diode Laser Hair Removal System is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin

	type I-VI), including tanned skin. 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.	type I-VI), including tanned skin. 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.	type I-VI), including tanned skin. 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.
Operation principle	Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy surrounding hair follicles, and finally remove hair.	Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy surrounding hair follicles, and finally remove hair.	Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy surrounding hair follicles, and finally remove hair.
Laser type	Diode laser	Diode laser	Diode laser
Laser classification	Class IV	Class IV	Class IV
Laser wavelength	808nm	808nm	808nm
Spot Size	1.44 cm^2	1.44 cm^2	1.44 cm^2
Fluence	2-120J/cm^2	2-120J/cm^2	1-120J/cm^2
Frequency	1-10Hz	1-10Hz	1Hz, 2Hz, 3Hz, 10Hz
Pulse Duration	10-300ms	9-143ms	2.9-348ms
Power supply	100-240V AC, 50/60Hz	AC110V/50-60Hz	AC110V, 60Hz
Dimension	KM200D 60*42*38cm	42*63*54cm	38*54*120cm
	KM300D 60*42*35cm		
	KM600D 60*42*35cm		
	KM800D 60*42*40cm		
	KM900D 55*42*30cm		
Weight	35kg	30kg	55kg
Patient contact material	Sapphire in handpiece and handpiece tip (stainless steel)	Sapphire in handpiece and handpiece tip (stainless steel)	Sapphire in handpiece and handpiece tip (stainless steel)
Biocompatibility	Comply with ISO10993-1	Comply with ISO10993-1	Comply with ISO10993-1

Electrical Safety	Comply with IEC60601-1, IEC60601-2-22	Comply with IEC60601-1, IEC60601-2-22	Comply with IEC60601-1, IEC60601-2-22
EMC	Comply with IEC60601-1-2,	Comply with IEC60601-1-2,	Comply with IEC60601-1-2,
Laser safety	Comply with IEC60825-1, IEC60601-2-22	Comply with IEC60825-1, IEC60601-2-22	Comply with IEC60825-1, IEC60601-2-22

VII Performance data

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

Biocompatibility testing

Biocompatibility of the Laser Treatment System was evaluated in accordance with ISO 10993-1:2009 for the body contact category of “Surface – Mucosal Membrane” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation and Sensitization. All evaluation acceptance criteria were met

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Laser Treatment System. The system has been tested to comply with the following standards:

- IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22:2007, 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: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.

VIII Conclusion

The Diode Laser Treatment System is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.