DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 19, 2014

Global Medical Technology S.L.
% Mr. George J. Hattub
Medicsense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K140668
Trade/Device Name: PlatinumGMT™ IPL System Cloud
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: November 16, 2014
Received: November 24, 2014

Dear Mr. Hattub:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K140668:

Device Name: PlatinumGMT™ IPL System Cloud

Indications For Use: The PlatinumGMT™ IPL System Cloud device (inclusive of the hand piece used to deliver pulsed-light energy) is indicated for use in surgical, aesthetic and cosmetic applications in permanent hair reduction, moderate inflammatory acne vulgaris, benign cutaneous pigmented and vascular lesions.

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 regimen.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the office of Device Evaluation (ODE) guidance concerting the organization and content of a 510(k) summary.

The assigned 510(k) Number: K140668

1. Date of Submission: December 5, 2014

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: PlatinumGMT™ IPL System Cloud
Classification: Class II
Product Code: ONF
Regulation Number: 21 CFR 878.48 I 0
Review Panel: General and Plastic Surgery

Indications for Use

The PlatinumGMT™ IPL System Cloud device (inclusive of the hand piece used to deliver pulsed-light energy) is indicated for use in surgical, aesthetic and cosmetic applications in permanent hair reduction, moderate inflammatory acne vulgaris, benign cutaneous pigmented and vascular lesions.

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 regimen.

	Filter Setting and Wavelength Range	**Skin Types**				
Condition		**I**	**II**	**III**	**IV**	**V**
Hair Reduction		695-1200	695-1200	695-1200	695-1200	755-1200
Acne		430-1200	430-1200	430-1200	430-1200	----------
Vascular Lesions		560-1200	560-1200	560-1200	560-1200	----------
Pigmented Lesions		560-1200	560-1200	560-1200	560-1200	----------

5. Predicate Device Identification

510(k) Number: K131859
Product Name: Multifunctional Series
Manufacturer: Beijing Honkon Technologies Co., Ltd.
510(k) Number: K122995
Product Name: Intense Pulse Light (IPL) Systems/ MED-210/230
Manufacturer: Beijing Kes Biology Technology Co., Ltd.

6. Device Description

The PlatinumGMT™ IPL System Cloud device is an intense pulsed light system which delivers intense pulsed light at a wavelength ranging from 560 nm-1200 nm. Intense Pulsed Light (IPL) systems work on the principles of selective thermolysis. That is, causing thermal damage to target chromophores by using light of appropriate wavelength in pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin.

IPL Systems are different from lasers in that they deliver many wavelengths in each pulse of light instead of just one wavelength. Generally, IPL enhances penetration without using excessive energy levels and enables targeting of specific chromophores. Based on this, the PlatinumGMT™ IPL System Cloud device (inclusive of the hand piece used to deliver pulsed light energy) is indicated for use in surgical, aesthetic and cosmetic applications in permanent hair reduction, moderate inflammatory acne vulgaris, benign cutaneous pigmented, and vascular lesions.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed device complies with the following:
(a) IEC 60601-1-2 Edition 3:2007-03, medical electrical equipment - Part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests

(b) IEC 60601-1. Medical Electrical Equipment- Part 1: General Requirements for Safety. 1988: Amendment I, 1991-II, Amendment 2, 1995.

(c) IEC 60335-2-27 ed 4.0 Household and similar electrical appliances - Safety - Part 2-27: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation

(d) IEC/EN 60335-1 Safety of household and similar electrical appliances – General

(e) EN 55014-1:2008 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus -- Part 1: Emission; Harmonics IEC 61000-3-2; Flicker IEC 61000-3-3

(f) EN 55014-2 (HHA Immunity Standard); Electrostatic Discharge IEC 61000-4-2 (±6kV Contact ±8kV Air); Radiated RF IEC 61000-4-3 (80 – 2500 MHz 3V/m); Electrical Fast Transients IEC 61000-4-4 (±2kV AC mains ±1kV other); Surge IEC 61000-4-5 (±1kV Differential ±2kV Common; Conducted RF IEC 61000-4-6 (3Vrms, 0.15 – 80 MHz); IEC 61000-4-11 Voltage Dips and Interrupts (>95%V for 0.5 Cycle 60%V for 5 Cycles).

(g) Performance Test (output energy, spot size)

8. Technological Characteristics Comparison

The proposed device has the same technological characteristics with the predicate devices, such as light medium, wavelength, control method and intended use.

9. Substantially Equivalent Conclusion

The wavelength range, energy density, pulse delays and duration of the proposed device are similar to the predicate devices, the slight differences are not considered to affect safety and efficacy.

Based on the comparison and analysis below, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.

Substantial Equivalence Comparison

ITEM	Proposed Device PlatinumGMT™ IPL System (CLOUD)	Predicate Device Multifunctional Series (K131859)	Predicate Device Intense Pulsed Light (IPL) Systems (K122995)
Product Code	ONF	ONF	ONF
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Class	II	II	II
Intended Use	The PlatinumGMT™ IPL System Cloud device (inclusive of the hand piece used to deliver pulsed light energy) is indicated for use in surgical, aesthetic and cosmetic applications in permanent hair reduction; moderate inflammatory acne , benign cutaneous pigmented, and vascular lesions. 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 regimen	The Multifunctional Series device (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in hair removal, moderate inflammatory acne vulgaris, and benign cutaneous vascular lesions.	The Intense Pulsed Light (IPL) Systems (inclusive of the handpiece used to deliver pulsed-light energy) are indicated for use in surgical, aesthetic and cosmetic applications in permanent hair reduction, treatment of pigmented lesions, moderate inflammatory acne vulgaris, ephelides (freckles), and vascular lesions
Light Source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light
Wavelength	430-1200nm	530-1200nm	430-1200nm
Delivery System	Sapphire	Sapphire	Sapphire
Energy Range	10-60J/cm2	20-50J/cm2	10-60J/cm2

Pulse Delay	1-99ms	0.1-40ms	5-50ms
Pulse Duration	1-9.9 ms	1-25ms	1-14ms
Maximum Power	1200W	2000W	1400W (MED-210) 2000W (MED-230)
Power Supply	AC 230V +/- 20V 50Hz/60Hz 12A	unknown	220V+/-20V 50Hz 110V+/-20V 60Hz
Spot Size	10 x 45mm & 8 x 34 mm	8 x 40mm & 15 x 60mm	12 x 33mm; 15 x 50mm & 15 x 35mm

Settings for Specific Indications for Use- Hair Reduction			
	Proposed Device PlatinumGMT™ IPL System (CLOUD	**Predicate Device Multifunctional Series (K131859)**	**Predicate Device Intense Pulsed Light (IPL) Systems (K122995**)
Wavelength (mm)	695 -1200	610-1200	640-1200
Energy Range (J/cm2)	10-60	20-50	10-44
Pulse Duration (ms)	9.9	13-15	3-14
Pulse Delay (ms)	1-99	15-35	16-32
Spot Size (mm)	10 x 44	8 x 40 15 x 60	12 x 33 15 x 50 15 x 35

Settings for Specific Indications for Use- Treating Acne			
	Proposed Device PlatinumGMT™ IPL System (CLOUD	**Predicate Device Multifunctional Series (K131859)**	**Predicate Device Intense Pulsed Light (IPL) Systems (K122995**)
Wavelength (mm)	430-1200	530-1200	430-1200
Energy Range J/cm2	10-40	20-50	10-40
Pulse Duration (ms)	3-8	3-10	3-8
Pulse Delay (ms)	16-32	15-35	16-32
Spot Size (mm)	8 x 34	8 x 40 l5 x 60	12 x 33 15 x 50 15 x 35

Settings for Specific Indications for Use Vascular Lesions			
	Proposed Device PlatinumGMT™ IPL System (CLOUD	**Predicate Device Multifunctional Series (K131859)**	**Predicate Device Intense Pulsed Light (IPL) Systems (K122995**)
Wavelength (mm)	560-1200	585-1200	530-1200
Energy Range J/cm2	10-50	20-50	10-42
Pulse Duration (ms)	9.9	3-10	3-8
Pulse Delay (ms)	16-32	15-35	16-32
Spot Size (mm)	8 x 34	8 x 40 l5 x 60	12 x 33 15 x 50 15 x 35

Settings for Specific Indications for Use Pigmented Lesions			
	Proposed Device PlatinumGMT™ IPL System (CLOUD	**Predicate Device Multifunctional Series (K131859)**	**Predicate Device Intense Pulsed Light (IPL) Systems (K122995**)
Wavelength (mm)	560-1200	Not cleared	480-1200
Energy Range J/cm2	12-44	Not cleared	12-44
Pulse Duration (ms)	3-9	Not cleared	3-9
Pulse Delay (ms)	16-32	Not cleared	16-32
Spot Size (mm)	8 x 34	Not cleared	12 x 33 15 x 50 15 x 35