May 20, 2024

Shanghai Bele Medical Technology Co., Ltd
Jeremy Li
Room 402, 4F, Building 1, NO.3255 Shengang Road,
Songjiang District
Shanghai, Shanghai 201600
China

Re: K240474
Trade/Device Name: Multi-function Platform Systems (BL-M10)
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, ONF
Dated: April 30, 2024
Received: April 30, 2024

Dear Jeremy Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S

Digitally signed by Tanisha L. Hithe -S
Date: 2024.05.20 15:18:25 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240474

Device Name
Multi-function Platform Systems (BL-M10)

Indications for Use *(Describe)*
(1) IPL: The Therapy IPL is intended for medical use in the treatment of the following dermatologic conditions: - Permanent hair reduction- long-terms table reduction in number of hairs re-growing after a treatment regimen; - Moderate inflammatory acne vulgaris; - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles); - Cutaneous lesions including scars; - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations.
(2) Diode laser: Diode laser treatment handpiece (808nm) handset is indicated for permanent reduction in hair regrowth defined as a 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. It is suitable for all skin types (Fitzpatrick skin type I-VI), including tanned skin.
3) Triple Diode laser: The device is intended for use in dermatologic and general surgical procedures.
The Triple diode laser Module is intended for use in dermatology procedures requiring coagulation. The Triple diode laser Module is indicated for: - Benign vascular and vascular dependent lesions removal.
(4) Picosecond Nd:YAG Laser: The Picosecond Nd:YAG Laser is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. - The 1064nm wavelength of the Picosecond Nd:YAG Laser is indicated for tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI). - The 532nm wavelength of the Picosecond Nd:YAG Laser is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types 1-III.
(5) 1064nm Long pulse Nd:YAG: The 1064nm Long pulse Nd:YAG is indicated for - Benign vascular lesions. - Superficial and deep telangiectasias (venulectasias). - Benign cutaneous lesions. - Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. - The non-ablative treatment of facial wrinkles. - Laser skin resurfacing procedures. - Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. - Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. - Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. - Removal or lightening of unwanted hair (with and without adjuvant preparation). - Treatment of pseudofolliculitis barbae (PFB).
(6) Q-switch Nd:YAG laser: The Q-switch Nd:YAG Laseris Module indicated for: -Benign vascular and pigmented lesions, age spots. - Nevus spilus. - Tattoo removal.

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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510(k) Summary

I. Submission

Submission Number **K240474**

Device submitter Shanghai Bele Medical Technology Co. Ltd.
Room 402, 4F, Building 1, NO.3255 Shengang Road, Songjiang District, Shanghai, China

Contact Person Jeremy Li

Phone Number +86-21 51012882

Email jeremy@belemed.com

Submission Date May 16, 2024

II. Device Information

Trade Name Multi-function Platform Systems (BL-M10)

Common Name Laser surgical instrument for use in general and plastic surgery and in dermatology

Classification Name Powered Laser Surgical Instrument

Regulation Number 21 CFR 878.4810

Product Code GEX, ONF

III. Predicate Devices

Trade Name of Device:	IPL Treatment System
Common name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification:	Class II, 21 CFR 878.4810.
Product Code:	ONF
Premarket Notification:	K200746
Company name:	Shanghai Apolo Medical Technology Co., Ltd.

Trade Name of Device:	Diode Laser Therapy Device
Common name:	Powered Laser Surgical Instrument
Classification:	Class II, 21 CFR 878.4810
Product Code:	GEX
Premarket Notification:	K200118
Company name:	Shanghai Apolo Medical Technology Co., Ltd.

Trade Name of Device:	Modified Alma Lasers Soprano XL™ Family ofMulti-Application & MultiTechnology Platforms [SopranoXL, SopranoXLi, SopranoICE and Soprano ICE Platinum] with Duo and Trio Diode Laser Modules., Soprano Duo and Trio

	Diode Laser Modules
Common name:	Laser Powered Surgical Instruments (& Accessories)
Classification:	Class II, 21 CFR 878.4810.
Product Code:	GEX, ILY
Premarket Notification:	K172193
Company name:	Alma Lasers Inc.

Trade Name of Device:	PICOSECOND Nd:YAG Laser System
Common name:	/
Classification:	Class II, 21 CFR 878.4810.
Product Code:	GEX
Premarket Notification:	K233018
Company name:	IDS, Ltd.

Trade Name of Device:	Platform treatment system
Common name:	Powered Laser Surgical Instrument
Classification:	Class II, 21 CFR 878.4810.
Product Code:	ONF, GEX
Premarket Notification:	K203395
Company name:	Shanghai Apolo Medical Technology Co., Ltd.

Trade Name of Device:	MT ONE
Common name:	Intense Pulsed Light(IPL) and laser System
Classification:	Class II, 21 CFR 878.4810.
Product Code:	GEX, ONG, ONF, ONE
Premarket Notification:	K192856
Company name:	M&TS.R.L.

IV. Device description

The BL-M10 is a new platform treatment system with 12.1" display screen which combines IPL/ Diode Laser/Triple Diode Laser/ Picosecond Nd:YAG Laser/ 1064nm Long pulse Nd:YAG laser and Q-switch Nd:YAG Laser functions. This is 6 in 1 platform machine, that provides different function with attaching different hand pieces. The system is designed with a mains electricity (AC-powered) mobile (on wheels) assembly of devices that uses multiple therapeutic modalities in combination or in isolation for ablative and non-ablative treatment of skin surface. The system includes various energy sources and dedicated hand-pieces intended to apply the different energies to the skin for respective indications for use.

V. Indications for use

(1) IPL: The Therapy IPL is intended for medical use in the treatment of the following dermatologic conditions: - Permanent hair reduction- long-terms table reduction in number of hairs re-growing after a treatment regimen; - Moderate inflammatory acne vulgaris; - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles); - Cutaneous lesions including scars; - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations.

(2) Diode laser: Diode laser treatment handpiece (808nm) handset is indicated for permanent reduction in hair regrowth defined as a 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. It is suitable for all skin types (Fitzpatrick skin type I-VI), including tanned skin.

(3) Triple Diode laser: The device is intended for use in dermatologic and general surgical procedures. The Triple diode laser Module is intended for use in dermatology procedures requiring coagulation. The Triple diode laser Module is indicated for:

- Benign vascular and vascular dependent lesions removal.

(4) Picosecond Nd:YAG Laser: The Picosecond Nd:YAG Laser is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. - The 1064nm wavelength of the Picosecond Nd:YAG Laser is indicated for tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI). - The 532nm wavelength of the Picosecond Nd:YAG Laser is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.

(5) 1064nm Long pulse Nd:YAG: - Benign vascular lesions - Superficial and deep telangiectasias (venulectasias) - Benign cutaneous lesions - Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. - The non-ablative treatment of facial wrinkles. - Laser skin resurfacing procedures. - Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. - Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. - Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. - Removal or lightening of unwanted hair (with and without adjuvant preparation). - Treatment of pseudofolliculitis barbae (PFB).

(6) Q-switch Nd:YAG laser: The Q-switch Nd:YAG Laseris Module indicated for: • Benign vascular and pigmented lesions, age spots • Nevus spilus • Tattoo removal

VI. Comparison of Technological Characteristics with Predicate Devices

The Multi-function Platform Systems (BL-M10) shares the same technological characteristics as its predicate devices, including energy sources (laser/IPL), control mechanisms, and core specifications.

Tabel 1 Substantial equivalence discussion - IPL

Device feature	IPL (subject device)	IPULSELIGHT IPL SYSTEM K200746 (predicate device)	Discussion
Intended use	The Therapy IPL is intended for medical use in the treatment of the following dermatologic conditions: - Permanent hair reduction- long-terms table reduction in number of hairs re-growing after a treatment regimen; - Moderate inflammatory acne vulgaris; - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles); - Cutaneous lesions including scars; - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations.	The IPL treatment systems is intended for medical use in the treatment of the following dermatologic conditions: - Permanent hair reduction- long-terms table reduction in number of hairs re-growing after a treatment regimen; - Moderate inflammatory acne vulgaris; - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles); - Cutaneous lesions including scars; - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations.	Identical
Light source	Intense pulsed light (Xenon Flash Lamp)	Intense pulsed light (Xenon Flash Lamp)	Identical
Wavelength	Filters:	Filters:	Identical

Device feature	IPL (subject device)	IPULSELIGHT IPL SYSTEM K200746 (predicate device)	Discussion
Range	420 -1200nm: Acne; 510 -1200nm: Acne, vascular, pigment; 560 -1200nm: Acne, vascular, pigment; 610-1200nm: Hair removal; 640-1200nm: Hair removal; 690-1200nm: Hair removal;	420 -1200nm: Acne; 510 -1200nm: Acne, vascular, pigment; 560 -1200nm: Acne, vascular, pigment; 610-1200nm: Hair removal; 640-1200nm: Hair removal; 690-1200nm: Hair removal;	
Handpiece Ports	IPL treatment handpiece	HS-650K&HS-660K: 2 HS620K, HS-300CK & HS-310K: 1	Different 1
Structure	Vertical	HS-650K&HS-660K: Vertical HS620K, HS-300CK & HS-310K: Table top	Different 2
Energy output	10-50 J/cm^2	4.1-50.8 J/cm^2	Different 3
Pulse width	2-20ms	5-20 ms	Different 4
Pulse duration	5-50 ms	5-50 ms	Identical
Spot size	15mm×50mm	12*35mm, 15*50mm	Different 5
Output mode	Pulse mode	Pulse mode	Identical
Deliver materials	Direct sapphire Coupling	Direct sapphire Coupling	Identical
Cooling method	Water cooling, forced-air cooling and TEC water tank cooling system and semiconductor chip	HS-650K&HS-660K: Water cooling, forced-air cooling, copper and TEC; HS620K, HS-300CK&HS-310K: Water cooling and forced-air cooling,	Different 7

Conclusion:

- Handpiece Ports: The subject device has one IPL treatment handpiece port, while the

predicate device offers multiple handpiece ports depending on the model. However, this difference in handpiece ports does not affect the intended use of the device, as both devices are capable of delivering the required treatments with their respective handpieces.

- Energy Output: The energy output ranges of both devices are within similar ranges, with the subject device ranging from 10-50 J/cm² and the predicate device ranging from 4.1-50.8 J/cm². While there is a difference in the upper limit of the energy output, both devices offer sufficient energy levels for effective treatment across various dermatologic conditions.
- Pulse Width: The subject device offers pulse widths ranging from 2-20ms, whereas the predicate device offers pulse widths ranging from 5-20 ms, which are basically similar. These differences in pulse parameters are minor and do not significantly impact the intended use of the devices for dermatologic treatments.
- Spot Size: The subject device offers a spot size of 15mm×50mm, covered by the predicate.

Tabel 2 Substantial equivalence discussion - Diode Laser

Device feature	**Diode Laser (subject device)**	**Diode Laser Therapy Device K200118 (predicate device)**	**Discussion**
Intended use	Diode laser treatment handpiece (808nm) handset is indicated for permanent reduction in hair regrowth defined as a 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. It is suitable for all skin types (Fitzpatrick skin type I-VI), including tanned skin.	The Diode Laser Therapy Device is indicated for permanent reduction in hair regrowth defined as a 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. It is suitable for all skin types (Fitzpatrick skin type I-VI), including tanned skin.	Identical
Spot Size	12mm×23mm	12x16mm; 12x20mm	Different 1
Energy Source	808nm diode laser	755nm handpiece 810nm handpiece 1064nm handpiece	Different 2
Wavelength	808nm	755nm/810nm/1064nm	Different 3

Device feature	Diode Laser (subject device)	Diode Laser Therapy Device K200118 (predicate device)	Discussion
		for option	
Maximum Repetition Rate	1,2,3,5,8,10Hz	1,2,3,5,8,10Hz	Similar
Pulse Duration	10-300ms	10-300ms	Identical
Energy	1-62J/cm^2	1~64J/cm2 1~62J/cm2	Different 4

Conclusion:

- Different 1:

  Spot Size: The subject device has a larger spot size (12mm×23mm) compared to the predicate device. A larger spot size can affect the treatment speed and efficiency, reducing treatment time.

- Different 2&3:

  Energy Source (Wavelength): Both the subject device and the HS-817 & HS-819 models of the predicate device operate with diode lasers in the 808nm to 810nm range. This slight difference in wavelength (808nm for the subject device vs. 810nm for the predicate models) is minimal and likely does not affect the efficacy or safety profiles of the devices significantly. Operating in a similar near-infrared spectrum, they are expected to have comparable penetration depths and effects on hair follicles, ensuring a similar mechanism of action for hair removal.

- Different 4

  The subject device operates with an energy range of 1-62 J/cm², which is slightly lower than the maximum value of 64 J/cm² for one of the settings of the predicate device. This variation in maximum energy output may affect the ability of the device to adapt to different hair densities and skin types. A lower maximum energy may mean that the emphasis on comfort and minimising skin irritation is beneficial for sensitive skin types or for use on more delicate areas.

Both the subject and the predicate devices share the primary function of hair removal, employing diode lasers to achieve this end. Despite minor variations in their specifications, such as energy output and spot size, the core technology remains consistent, suggesting a substantial equivalence in therapeutic outcome. Therefore, the differences identified do not raise concerns regarding the intended use or safety of the subject device.

Tabel 3 Substantial equivalence discussion - Triple Diode laser

Device feature	**Triple Diode laser (subject device)**	**Modified Alma Lasers Soprano XL™ Family ofMulti-Application & MultiTechnology Platforms [SopranoXL, SopranoXLi, SopranoICE and Soprano ICE Platinum] with Duo and Trio Diode Laser Modules., Soprano Duo and Trio Diode Laser Modules K172193 (predicate device)**	**Discussion**
Intended use	Intended Use The device is intended for use in dermatologic and general surgical procedures. Indications for Use The triple diode laser Module is intended for use in dermatology procedures requiring coagulation. The Triple diode laser Module is indicated for: ● Benign vascular and vascular dependent lesions removal.	Intended Use The device is intended for use in dermatologic and general surgical procedures. Indications for Use The Soprano trio Diode Laser Module is intended for use in dermatology procedures requiring coagulation. The indications for use for the Soprano Trio Diode Laser Module include: ● Benign vascular and vascular dependent lesions removal.	Identical
Spot Size	12mm×23mm	Trio 4 cm^2 applicator Trio 2 cm^2 applicator	Different 1
Wavelength	755/808/1064nm	755/808/1064nm	Identical
Maximum Repetition Rate	1~10Hz	1-10 Hz	Identical

Device feature	Triple Diode laser (subject device)	Modified Alma Lasers Soprano XL™ Family ofMulti-Application & MultiTechnology Platforms [SopranoXL, SopranoXLi, SopranoICE and Soprano ICE Platinum] with Duo and Trio Diode Laser Modules., Soprano Duo and Trio Diode Laser Modules K172193 (predicate device)	Discussion
Pulse Duration	10-130ms	3.3-280 ms	Different 2
Energy	1~32J/cm^2	up to 60 J/cm^2	Different 3

Conclusion:

- Different 1:
  Spot Size: The subject device's spot size of 12mm×23mm (2.76cm²) is different from the predicate device's options of 4cm² and 2cm², but is within the range of the predicate device.
- Different 2:
  Pulse Duration: The subject device offers pulse duration within the range covered by the predicate.
- Different 3:
  Energy: The subject device offers energy level covered by the predicate.

In conclusion, the differences in some parameters between the subject device and the predicate device are minor. The core technology and operational principles remain consistent, ensuring that the subject device is substantially equivalent to the predicate device.

Tabel 4 Substantial equivalence discussion - Picosecond Nd:YAG Laser

Device feature	Picosecond Nd:YAG Laser (subject device)	PICOSECOND Nd: YAG Laser System K233018 (predicate device)	Discussion
Intended use	The Picosecond Nd:YAG Laser is intended for use in	The PICOSECOND Nd: YAG Laser System (PICO	Identical

Device feature	Picosecond Nd:YAG Laser (subject device)	PICOSECOND Nd: YAG Laser System K233018 (predicate device)	Discussion
	surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. - The 1064nm wavelength of the Picosecond Nd:YAG Laser is indicated for tattoo removal for dark-colored tattoo inks and multicolored tattoos containing dark-colored tattoo inks on patients with all skin types (Fitzpatrick I-VI). - The 532nm wavelength of the Picosecond Nd:YAG Laser is indicated for tattoo removal for lighter-colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.	PREMIUM) is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery. - The 1064nm wavelength of the PICOSECOND Nd: YAG Laser System (PICO PREMIUM) is indicated for tattoo removal for dark-colored tattoo inks and multicolored tattoos containing dark-colored tattoo inks on patients with all skin types (Fitzpatrick I-VI). - The 532nm wavelength of the PICOSECOND Nd: YAG Laser System (PICO PREMIUM) is indicated for tattoo removal for lighter-colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.	
Spot Size	1, 2, 3, 4, 5, 7 mm	2mm - 10mm (Adjustable by 1mm) - Both Modes	Different 1
Wavelength	Double wavelength	532 or 1064nm (+/-10%)	Identical

Device feature	Picosecond Nd:YAG Laser (subject device)	PICOSECOND Nd: YAG Laser System K233018 (predicate device)	Discussion
	1064nm&532nm		
Maximum Repetition Rate	1-10Hz	1-10Hz (Adjustable by 1Hz)	Identical
Pulse Duration	< 980ps	300 ps - Both Modes	Different 2
Energy	50mJ to 400mJ(1064nm); 50mJ to 200mJ(532nm)	532nm mode: 50 - 250mJ (Adjustable by 25mJ) 1064nm mode: 100-500mJ (Adjustable by 25mJ)	Different 3

Conclusion:

- Spot Size: The subject device offers a spot size range of 1, 2, 3, 4, 5, 7 mm, while the predicate device provides a range of 2mm to 10mm, adjustable by 1mm. While the subject device's spot size range is narrower, both devices offer adjustable spot sizes suitable for various treatment areas.
- Pulse Duration: The subject device has a pulse duration of <980ps, while the predicate device offers a pulse duration of 300 ps in both modes. While there is a difference in pulse duration, both devices effectively deliver short pulses ideal for picosecond laser treatments.
- Energy: The subject device provides energy ranges for both 1064nm and 532nm wavelengths, while the predicate device offers adjustable energy levels for each wavelength mode. Both devices offer customizable energy settings suitable for various tattoo removal treatments.

Based on the analysis, there are differences between the subject and predicate devices in parameters such as spot size, wavelength presentation, pulse duration, and energy settings. However, these discrepancies do not significantly affect the intended use or safety of the subject device. Both devices effectively target tattoo pigments across different skin types and offer adjustable settings suitable for various treatment protocols. Therefore, while there are differences between the devices, they do not raise concerns regarding the intended use or safety of the subject device..

Tabel 5 Substantial equivalence discussion - 1064nm Long pulse Nd:YAG

Device feature	1064nm Long pulse Nd:YAG (subject device)	Platform treatment system K203395 (predicate device)	Discussion
Intended use	Indicated for - Benign vascular lesions. - Superficial and deep telangiectasias (venulectasias). - Benign cutaneous lesions. - Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. - The non-ablative treatment of facial wrinkles. - Laser skin resurfacing procedures. - Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. - Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. - Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. - Removal or lightening of unwanted hair (with and without adjuvant preparation). - Treatment of pseudofolliculitis barbae (PFB).	Indicated for - Benign vascular lesions. - Superficial and deep telangiectasias (venulectasias). - Benign cutaneous lesions. - Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. - The non-ablative treatment of facial wrinkles. - Laser skin resurfacing procedures. - Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. - Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. - Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. - Removal or lightening of unwanted hair (with and without adjuvant preparation). - Treatment of pseudofolliculitis barbae (PFB).	Identical
Energy Source	1064nm Long pulse Nd:YAG	1064 nm Long Pulse (LP) Nd:YAG Laser	Identical
Spot Size	2x5mm, ₵6mm, ₵9mm	2.2x5mm, ₵6mm, ₵9mm	Similar
Wavelength	1064nm	1064nm	Identical
Maximum Repetition Rate	1Hz	1Hz	Identical
Pulse Duration	10-40ms	10 ~ 40ms	Identical
Energy	10 ~ 500 J/ cm2	10 ~ 500 J/ cm2	Identical

Conclusion:

The comparison between the 1064nm Long pulse Nd:YAG (subject device) and the Platform Treatment System shows same indication for use and same fundamental technological features, including energy source, spot size, wavelength, maximum repetition rate, and pulse duration, indicating that both devices are equipped with similar capabilities for treating a range of skin conditions.

Tabel 6 Substantial equivalence discussion - Q-switch Nd:YAG Laser

Device feature	Q-switch Nd:YAG Laser (subject device)	MT ONE K192856 (predicate device)	Discussion
Intended use	The Q-switch Nd:YAG Laseris Module indicated for: • Benign vascular and pigmented lesions, age spots • Nevus spilus • Tattoo removal	MT ONE with 532/1064 nm Nd:YAG Q-Switch Laser Handpiece is indicated for: • Benign vascular and pigmented lesions, age spots • Nevus spilus • Tattoo removal	Identical
Energy Source	Q-Switched ND:YAG	Q-Switched Laser	Identical
Spot Size	1, 2, 3, 4, 5, 7 mm	1, 2, 3, 4, 5, 8 mm	Similar
Wavelength	532/1064nm	532/1064nm	Identical
Maximum Repetition Rate	1/2/3/4/5/6/6/7/8/9/10Hz	up to 10Hz	Identical
Pulse Duration	<10ns	15ns	Similar
Energy	1064nm:360-2000mJ 532nm:180-1000mJ	2000mJ (4J/cm(1064 nm) φ8mm 1600mJ (3.2J/cm2(532 nm)φ8mm	Different 1

Conclusion:

- Intended use: Both devices are intended for the same applications.
- Spot Size: The subject device offers a spot size range of 1-5mm, while the predicate device provides options of 1, 2, 3, 4, 5, and 8mm. While the specific spot sizes differ slightly, the predicate device's range encompasses the spot size options of the subject device, indicating containment.
- Maximum Repetition Rate: The maximum repetition rate of the subject device is less than 10 ns, whereas the predicate device specifies a repetition rate of 15 ns. The subject device parameters are included in the specified parameters of the predicate device.
- Energy: The subject device provides energy ranges of 360-2000mJ for 1064nm and 180-1000mJ for 532nm, while the predicate device specifies energy levels of 3.2 J/ cm² for 532nm and 4 J/cm² for 1064nm, which are similar energy levels.

Based on the analysis, while there are differences between the subject and predicate devices in certain parameters such as spot size and maximum repetition rate, these discrepancies do not significantly impact the intended use or safety of the subject device. The predicate

device's specifications encompass those of the subject device, ensuring compatibility and effectiveness in treating skin lesions and pigmentation issues. Therefore, the differences identified do not raise concerns regarding the intended use or safety of the subject device.

VII.Performance data

VII.1. Non-Clinical Testing:

A battery of tests was performed to verify that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:
Electrical safety and electromagnetic compatibility

- IEC 60601-1: 2005+corr.1:2006+Corr.2.2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-22:2007+A1: 2012 Medical electrical equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements
- IEC 62471:2006 Photobiological safety of lamps and lamp systems
- IEC 60601-2-57:2011 Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

Non-Clinical testing of the Multi-Function Platform Systems (BL-M10) was conducted to assess the safety and performance characteristics of the device's multiple handpieces. These tests were designed to demonstrate compliance with established standards and to support claims of substantial equivalence to the respective predicate devices.
Test Categories and Results:
1. Electrical Safety and Electromagnetic Compatibility
- Compliance with IEC 60601-1 for basic safety and essential performance.
- Testing per IEC 60601-1-2 for electromagnetic compatibility demonstrated that the BL-M10 does not emit harmful interference and is immune to typical electromagnetic disturbances in its intended environments.

VII.2. Performance Testing

- Each handpiece underwent rigorous performance testing to verify adherence to specified energy output, wavelength accuracy, pulse duration, and spot size.
- The testing confirmed that all handpieces meet or exceed the performance characteristics of their predicate devices.

VII.3. Laser and Light Safety

- Tests conducted under IEC 60601-2-22 for laser safety and IEC 62471 for photobiological safety, ensuring that both patient and operator are protected from potential hazards of laser and light exposure.

- The device's safety features, such as emergency shut-off and controlled access mechanisms, were verified to function correctly under all tested conditions.

VIII. Clinical Testing

Not Applicable.

IX. Conclusion

Based on the comparison and substantial equivalence discussion provided, the Multi-function Platform Systems (BL-M10) is substantially equivalent to its predicate devices. The differences identified do not raise concerns regarding the intended use or safety of the subject device. The core technology and operational principles remain consistent, ensuring effective and safe treatment outcomes.