October 8, 2025

Bellamia Technologies, Inc.
Ahmed Mohammed
VP Quality and Regulatory
285 W Central Pkwy, Suite 1735
Altamonte Springs, Florida 32714

Re: K251699
Trade/Device Name: The Botticelli (Model: Athena)
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
Dated: June 1, 2025
Received: June 2, 2025

Dear Ahmed Mohammed:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.10.08 23:50:41 -04'00'

for Tanisha Hithe
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251699

Device Name
The Botticelli (Model: Athena)

Indications for Use *(Describe)*
1470 nm Laser: Dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.

1927 nm Laser: The Botticelli (Model: Athena) is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

2910 nm Laser: The Botticelli (Model: Athena) with its accessories is intended for use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle), such as, but not limited to: Dermatology and plastic Surgery: Skin resurfacing Treatment of wrinkles; Scar revision (including acne scars).

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

510(k) number	K251699
Device Trade Name	The Botticelli (Model: Athena)
Device Common Name	Laser Powered Surgical Device
Device Classification Name	Powered Laser Surgical Instrument
510(k) Type	Traditional
Applicant	BellaMia Technologies, Inc. 285 W Central Pkwy, Altamonte Springs, FL 32714
Applicant Contact	Name: Ahmed Mohammed Phone: 763-439-4602 Email: amohammed@bellamiatechnologies.com
Date Prepared	07-Oct-2025
Medical Specialty	General and Plastic Surgery
Regulation	§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.
Product Code	GEX (Class 2) – Powered Laser Surgical Instrument
Predicate Devices	**Medical diode laser systems (CHARISMA, REGAL) [K234004]** Regulation Number: 878.4810 Classification Product Code: GEX **LASEMD Laser System [K171009]** Regulation Number: 878.4810 Classification Product Code: GEX **JOULE ProFractional System SYSTEM [K180508]** Regulation Number: 878.4810 Classification Product Code: GEX

Device Description

The Botticelli Laser System is a cart-based device containing three individual lasers. The Botticelli is designed for ease of use and offers a small footprint. The system includes the 24" touch screen, on/off switch, foot switch, an emergency-stop button, remote interlock, and calibration port.

The device (the cart) houses the power consuming components, including the laser modules, power supplies, the scanner drivers, software, TEC cooling module, water pump, fans, software controls, and all other electrical control components. The cart also includes the plume evacuator and the skin cooling air chiller.

The 1470 nm laser subsystem is a diode laser that is coupled to a fiber to deliver treatment energy via a handpiece. A 450 nm visible blue laser diode aiming beam is used to visualize the location of the beam during laser treatment.

The 1927 nm laser subsystem is a thulium fiber laser. The system incorporates a diode pumped thulium fiber to generate laser emissions. The laser energy is delivered during treatment via the handpiece. A 450 nm visible blue laser diode aiming beam is used to visualize the location of the beam during laser treatment.

The 2910 nm laser system is an erbium fiber laser. The system incorporates a diode pumped erbium doped fluoride glass fiber to generate laser emission. The laser energy is delivered during treatment via the handpiece. A 450 nm visible blue laser diode aiming beam is used to visualize the location of the beam during laser treatment.

Definitions

Microbeam: A single laser pulse characterized by a specific diameter and predetermined energy; it is synonymous with terms such as (Laser) Shot, Dot, and Spot.

Laser Pattern Density: The number of laser spots in a certain area divided by the maximum number of spots in the same area (as a percentage).

Spot Fluence: the laser energy density for a single laser spot

Average Fluence: the total fluence of the pattern area (calculated using the total number of spots, the energy of each spot, and the total area)

Energy Delivery

The Botticelli system efficiently delivers energy through a handpiece equipped with laser fibers. This handpiece features an internal telescopic mechanism that precisely focuses the laser beam to the designated spot size at the target area. Additionally, it contains integrated electronics that facilitate communication with the system's computer, enabling a feedback mechanism that ensures accurate positioning of the optics.

Microspots

The 1470 nm laser has three different spot sizes to choose from:

- 100 microns
- 150 microns
- 200 microns

The 1927 nm laser has three different spot sizes to choose from:

- 100 microns
- 150 microns
- 200 microns

The 2910 nm laser has two different spot sizes to choose from:

- 310 microns
- 430 microns

Device Specifications
Device Dimensions
Width: 15 in (38 cm)
Length: 32 in (82 cm)
Height: 43 in (110 cm)
Weight: ~ 300 lb. (135 Kg)
Electrical Specifications
Rated Voltage: 220 VAC
Rated Frequency: 60 Hz
Rated Current: 15 A
Electrical Safety Classification: Class I, Type BF
Power Cord Length: 15 ft (4.6 m)
Footswitch Cable Length: 15 ft (4.6 m)
Certification: IEC 60601-1, IEC 60601-1-2
Laser Specifications
1470nm Laser Output Class IV; 42 W, Operation Range: 0.5W – 15W
1927nm Laser Output Class IV; 18.4 W, Operating Range: 5W
2910nm Laser Output Class IV; 10 W, Operating Range: 10W
Environmental Requirements
Ambient Operating Temperature: 50 °F (10 °C) to 95 °F (35 °C), must be above dew point.
Maximum Humidity: 90%, non-condensing
Minimum 18 in (46 cm) distance from walls, to ensure full circulation of cooling air.
Maximum Operating Altitude: 5,000 ft (1,524 m)
Shipping and Storage (Non-Operational) Requirements
Storage Temperature: 39.2 °F (-4 °C) to 113 °F (50 °C), must be above dew point.
Maximum Humidity: 90%, non-condensing

Indications for Use

1470 nm Laser: Dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.

1927 nm Laser: The Botticelli (Model: Athena) is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

2910 nm Laser: The Botticelli (Model: Athena) with its accessories is intended for use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle), such as, but not limited to: Dermatology and plastic Surgery: Skin resurfacing Treatment of wrinkles; Scar revision (including acne scars).

Technological Comparison

1470 nm Laser

Specification	This Application	Predicate Device	Comparison
Ref. 510(k)	K251699	K234004	N/A
Product	The Botticelli Laser Platform 1470 nm Laser System	Medical diode laser systems (CHARISMA, REGAL)	N/A
Product Code	GEX	GEX	Same
Indications for Use	Dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines.	**CHARISMA:** Dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures. further indicated for treatment of benign pigmented lesions, such as, but not limited to lentigines (age spots), solar lentigos (sun spots), melasma, dyschromia, and for treatment of facial wrinkles and fine lines. -Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue -Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux -Further indicated for laser assisted lipolysis. **REGAL:** -Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue -Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux -Further indicated for laser assisted lipolysis.	The subject device indications for use are a subset of the indications for use of the predicate device.
CDRH Laser Class	Class 4	Class 4	Same
Energy Source	Diode Laser, CW, Pulsed	GaAlAs diode laser	Same
Laser Wavelength	1470nm	1470nm±10nm	Same
Output Power	0.5W to 15W	CHARISMA: 0.5W-15.0W (±10%)	Same
Display Screen	Yes	Yes	Same
Power Requirements	220 VAC/15A, 60 Hz	~100-240V, 50-60Hz, 350VA	Similar
Aiming Beam	450 nm <2.5 mW	Diode laser of 650nm, power＜2mW, adjustable brightness.	Similar

Specification	This Application	Predicate Device	Comparison
Delivery System	Fiber Optic	CHARISMA contact: fibers of 200µm, 400µm, 600µm with SMA905 connector; Non-contact: fibers	Similar
Cooling System	Water to Air	Air	Similar
Control System	Microprocessor	MCU (Micro Controller Unit)	Same
Pulse Width	10ms-2.5s	CHARISMA: 10ms-2.5s (General Mode)	Same
Repetition Rate	0.2 Hz – 50 Hz	CHARISMA: 0.2Hz-50Hz (General Mode)	Same
Energy Density per Microbeam	Up to 50 mJ	CHARISMA: Up to 50mJ (General Mode)	Same
Output Mode	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	Same
Laser Type	Laser diode	Laser diode	Same

1927 nm Laser

Specification	This Application	Predicate Device	Comparison
Ref. 510(k)	K251699	K171009	N/A
Product	The Botticelli Laser Platform 1927 nm Laser System	LASEMD Laser System	N/A
Product Code	GEX	GEX	Same
Indications for Use	The Botticelli (Model: Athena) is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).	The LASEMD Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).	Same
CDRH Laser Class	Class 4	Class 4	Same
Wavelength	1927 nm	1927 nm	Same
Laser Type	Thulium Laser	Thulium Laser	Same
Energy Source	1927 nm	1927 nm	Same
Spot Size	100, 150, 200 µm	100, 200 µm	Within Range
Pulse Repetition Rate	50-300 Hz	43.5 – 307.7 Hz	Within Range
Max Pulse Duration	20 ms	20 ms	Same
Tip Size (*)	4 mm x 10 mm	4 mm x 10 mm	Same
Max Pulse Energy	20 mJ	20 mJ	Same
Utilities	220 VAC/15A, 60 Hz	100-240 VAC, 50/60 Hz	Similar
Power	5 W (1927 nm)	5 W (1927 nm)	Same
Delivery System	Fiber and Handpiece	Fiber and Handpiece	Same
Emission Control	Footswitch	Footswitch	Same
Display Screen	Yes	Yes	Same
Cooling System	Air to Air	Air to Air	Same
Control System	Microprocessor	Microprocessor	Same
Energy Monitor	Display Indicates Energy Delivered to Tissue	Display Indicates Energy Delivered to Tissue	Same
Safety	Safety Eyewear and Remote Interlock Connector	Safety Eyewear and Remote Interlock Connector	Same

(*) The Botticelli 1927 nm has a rectangular tip (pattern) shape which is fixed to the 4 mm x 10 mm size.

2910 nm Laser

Specification	This Application	Predicate Device	Comparison
Ref. 510(k)	K251699	K180508	N/A
Product	The Botticelli Laser Platform 2910 nm Laser System	JOULE ProFractional System	N/A
Product Code	GEX	GEX	Same
Indications for Use	The Botticelli (Model: Athena) with its accessories is intended for use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle), such as, but not limited to: Dermatology and plastic Surgery: Skin resurfacing Treatment of wrinkles; Scar revision (including acne scars).	The Joule 2940 nm System with its accessories is intended for use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes; organs, and glands) such as, but not limited to: Dermatology and plastic Surgery: Skin resurfacing Treatment of wrinkles; Epidermal nevi; Telangiectasia; Spider veins; Actinic chelitis; Keloids; Verrucae; Skin tags; Anal tags; Keratoses; Scar revision (including acne scars).	The subject device indications for use are a subset of the indications for use of the predicate device.
Prescription Use	Yes	Yes	Same
Laser Energy Source	Er: YAG	Er: YAG	Same
Laser Delivery	Fiber, Handpiece	Fiber, Handpiece, Articulated arm	Similar
Wavelength	2910 nm	2940 nm	Similar
Adjustable Spot Size (Pattern Size)	1.3x1.3mm - 20x20mm	1.3x1.3mm - 20x20mm	Same
Micro spot size	310, 430 µm	430 µm	Similar
Repetition Rate (*)	Up to 3 Hz	Up to 3 Hz	Same
Pulse Width/ Duration	0.5 to 1.5 msec (or 1500 µsec)	0.5 to 1.5 msec (or 1500 µsec)	Same
Energy per Microbeam (mJ/mb)	Up to 35	Up to 70	Within Range
Fluence	0.15J/cm^2 to 8.4 J/cm^2	-	Similar
Target Chromophore	Water	Water	Same
Delivery System	Fiber optic with handpiece	Articulated arm and/or fiber optic arm with handpiece	Similar
Cooling System	Water & Air	Water & Air	Same
Electrical Requirements	220 VAC/15A, 60 Hz	230 VAC/25A, 50/60 Hz	Similar
Software/GUI/ Touch Screen	Yes	Yes	Same
Energy Monitor	Display Indicates Energy Delivered to Tissue	Display Indicates Energy Delivered to Tissue	Same

(*) The number of 'Patterns' per second, different from Pulses Per Second

Summary of Non-Clinical Testing

- Risk analysis activities, in compliance with the requirements of ISO 14971 Third Edition 2019-12. Medical devices - Application of risk management to medical devices
- IEC 60825-1:2014, Safety of laser products – Part 1: Equipment classification and requirements.
- IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance; IEC 60601-1:2005/AMD1:2012/AMD2:2020
- IEC 60601-1-2:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- Software verification and validations, in compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005 and Content of Premarket Submissions for Device Software Functions, June 2023.
- System Verification Testing

The tests confirmed that the subject device operates in alignment with its specifications and complies with international consensus standards and FDA guidance.

Conclusion

The Botticelli Laser System is substantially equivalent to its predicate devices. The nonclinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed devices.