November 25, 2025

SPECLIPSE. Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K253344
Trade/Device Name: BELLUS-Q
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: September 30, 2025
Received: September 30, 2025

Dear Janice Hogan:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253344

Device Name
BELLUS-Q

Indications for Use *(Describe)*
BELLUS-Q, Q switched Nd:YAG Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

1064 nm wavelength in Q-switched mode:
-Removal of dark (black, blue, brown) tattoo ink
-Treatment of nevus of ota
-Treatment of common nevi
-Removal and lightening of unwanted hair
-Skin resurfacing procedures for the treatment of acne scars and wrinkles
-Treatment of melasma
-General dermatology indications: Incision, excision, ablation and vaporization of soft tissue

1064 nm wavelength in GENESIS mode:
-Treatment of wrinkles
-Treatment of mild to moderate inflammatory acne vulgaris

532 nm wavelength in Q-switched mode (nominal delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces):
-Red, tan, purple and orange tattoo ink removal
-Sky blue (light) tattoo ink removal
-Green tattoo ink removal
-Treatment of benign pigmented lesions including, but not limited to: cafe-au-lait birthmarks, solar lentigines, senile lentigines, senile lentigines, Becker's nevi, freckles, common nevi, nevus spilus
-Treatment of benign vascular lesion including, but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi
-Seborrheic Keratosis
-Treatment of post-inflammatory hyperpigmentation
-Skin resurfacing procedures for the treatment of acne scars and wrinkles
-Removal of epidermal pigmented lesions

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: K253344
[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(1)]

Nov. 19, 2025

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: SPECLIPSE, Inc.
- Address: #501, #502, #503, #504, #505, 232, Sandan-ro, Danwon-gu, Ansan-si, Gyeonggi-do, 15433, Republic of Korea
- Contact Name: Myung Seo Park
- Telephone No.: +82-31-698-2269
- Email Address: mspark@speclipse.com
- Registration No.: TBD

3. Identification of Proposed Device(s) [21 CFR 807.92(a)(2)]

510(k) Number	K253344
Trade/Device/Model Name	BELLUS-Q
Product Name	Nd:YAG Surgical Laser Equipment
Common Name	Laser Surgical Instrument
Regulation Name	Powered Laser Surgical Instrument
Regulation Number	21 CFR 878.4810
Classification Product Code	GEX
Device Class	II
510(k) Review Panel	General & Plastic Surgery

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

- Predicate device #1

510(k) Number	K202172
Trade/Device/Model Name	StarWalker
Common Name	Laser Surgical Instrument
Device Classification Name	Powered laser surgical instrument
Regulation Number	21 CFR § 878.4810
Classification Product Code	GEX
Device Class	Class II
510(k) Review Panel	General & Plastic Surgery

- Predicate device #2

510(k) Number	K241527
Trade/Device/Model Name	Pastelle Pro
Common Name	Laser Surgical Instrument
Device Classification Name	Powered laser surgical instrument
Regulation Number	21 CFR § 878.4810
Classification Product Code	GEX
Device Class	Class II
510(k) Review Panel	General & Plastic Surgery

These predicate devices have not been subject to a design-related recall.

5. Description of the Device [21 CFR 807.92(a)(4)]

The system consists of a power supply, laser resonator, touch LCD monitor, articulated arm, handpieces, foot switch, and laser protective eyewear. The system includes several safety features, including use of key switch, an interlock, emergency stop button, and need to press a footswitch in order to activate the laser. The main body transmits the laser energy through the articulating arm to the handpiece which is positioned above or in contact with the

treatment area. Five different handpieces can be attached to the articulated arm, the Zoom handpiece, Collimated handpiece, MLA handpiece, 585 Dye handpiece, and the 650 Dye handpiece. In addition, the system can operate in different modes, including single pulse, PTP, 3-pulse, 6-pulse, and genesis modes. Each handpiece integrates and aiming beam that shows the treatment area.

The Nd:YAG laser surgical system utilizes a solid-state laser medium of Nd:YAG at 1064 nm and KTP at 532 nm. The 1064 nm and 532 nm wavelengths interact with targeted skin cells or tissues, primarily leveraging the Photothermolysis Effect in Q-switched nanosecond pulse modes. This selective photothermolysis mechanism enables controlled thermal absorption within target chromophores, leading to coagulation, denaturation, or vaporization of melanin-containing cells while preserving surrounding tissues. The laser energy is effectively absorbed by pigmented lesions, allowing for precise and efficient treatment in dermatological applications.

The system also supports Dye handpieces, which enable the use of 585 nm and 650 nm wavelengths by converting 532 nm light. These wavelengths have greater absorption for different specific pigment-related lesions, expanding the system's versatility in medical and aesthetic procedures.

6. Indications for Use [21 CFR 807.92(a)(5)]

BELLUS-Q, Q switched Nd:YAG Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

- 1064 nm wavelength in Q-switched mode:

  -Removal of dark (black, blue, brown) tattoo ink
  -Treatment of nevus of ota
  -Treatment of common nevi
  -Removal and lightening of unwanted hair
  -Skin resurfacing procedures for the treatment of acne scars and wrinkles
  -Treatment of melasma
  -General dermatology indications: Incision, excision, ablation and vaporization of soft tissue

- 1064 nm wavelength in GENESIS mode:

  -Treatment of wrinkles

  -Treatment of mild to moderate inflammatory acne vulgaris

- 532 nm wavelength in Q-switched mode (nominal delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces):

  -Red, tan, purple and orange tattoo ink removal

  -Sky blue (light) tattoo ink removal

  -Green tattoo ink removal

  -Treatment of benign pigmented lesions including, but not limited to: cafe-au-lait birthmarks, solar lentigines, senile lentigines, senile lentigines, Becker's nevi, freckles, common nevi, nevus spilus

  -Treatment of benign vascular lesion including, but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi

  -Seborrheic Keratosis

  -Treatment of post-inflammatory hyperpigmentation

  -Skin resurfacing procedures for the treatment of acne scars and wrinkles

  -Removal of epidermal pigmented lesions

7. Substantial Equivalence

The subject device has a subset of the indications cleared for K202172, and all devices share the same intended use of laser use in dermatological surgical and aesthetic applications. The subject device has identical indications to predicate #1, in that it is a subset of the predicate device (it does not have the indications related to use in PICO mode). Predicate #2 has equivalent indications, although they do not match verbatim. In sum, the subject device has the same intended use as either of the predicates.

The technological characteristics between the subject and the predicate devices are similar. All devices have two primary wavelengths, 1064 and 532 nm. All devices have dye handpieces that can modify the 532 nm output to 585 or 650 nm (595 and 660 nm in K241527). All devices can be operated in various modes, including single pulse (termed Q-switched in K202172) and genesis (termed long pulsed in K202172). The subject device also contains additional modes that are equivalent to other modes available only in K241527, including PTP and multi-pulse modes. While the subject device has 3 and 6 multi-pulse mode options, K241527 has 2 and 3 multi-pulse options. The addition of a 6-pulse option does not raise different questions as the pulse energy remains within the cleared energy of Genesis mode. The predicates also have modes that are not part of the subject device – specifically, K202172 has PICO mode which uses pulse widths shorter than the subject device, and K241527 has DOE mode which treats a large, square area. The fact that the subject device does not include these modes does not raise any questions. Finally, the handpieces available in the subject device match those provided in K241527 and include Zoom, Collimation, MLA, and Dye, although the predicate also includes DOE handpiece.

[Table 3. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
K Number	K253344	K202172	K241527	-
Manufacturer	SPECLIPSE, Inc.	Fotona d.o.o.	WON TECH Co., Ltd.	-
Device Name	BELLUS-Q	StarWalker	Pastelle Pro	-
Product Code	GEX	GEX	GEX	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
510(k) Review Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Identical
Indications for Use	1064 nm wavelength in Q-switched mode: -Removal of dark (black, blue, brown) tattoo ink -Treatment of nevus of ota -Treatment of common nevi -Removal and lightening of unwanted hair -Skin resurfacing procedures for the treatment of acne scars and wrinkles -Treatment of melasma -General dermatology indications: Incision, excision, ablation and vaporization of soft tissue 1064 nm wavelength in GENESIS mode: -Treatment of wrinkles -Treatment of mild to moderate inflammatory acne vulgaris 532 nm wavelength in Q-switched mode (nominal	1064 nm wavelength in Q-switched mode: -Removal of dark (black, blue, brown) tattoo ink -Treatment of nevus of ota -Treatment of common nevi -Removal and lightening of unwanted hair -Skin resurfacing procedures for the treatment of acne scars and wrinkles -Treatment of melasma -General dermatology indications: Incision, excision, ablation and vaporization of soft tissue 1064 nm wavelength in long pulse mode: -Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI,	The Pastelle Pro system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. 1064nm in nanosecond mode, including microbeam handpieces: - Tattoo removal: dark ink (black, blue, and brown)- Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation - Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of melasma	Identical (subset of predicate #1)

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
	delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces): -Red, tan, purple and orange tattoo ink removal -Sky blue (light) tattoo ink removal -Green tattoo ink removal -Treatment of benign pigmented lesions including, but not limited to: cafe-au-lait birthmarks, solar lentigines, senile lentigines, senile lentigines, Becker's nevi, freckles, common nevi, nevus spilus -Treatment of benign vascular lesion including, but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi -Seborrheic Keratosis -Treatment of post-inflammatory hyperpigmentation -Skin resurfacing procedures for the	including tanned skin -Photocoagulation and hemostasis of benign pigmented and benign vascular lesions, such as, but not limited to, port wine stains, hemaongiomae, warts, telangiectasiae, rosacea, venus lake, leg veins and spider veins -Coagulation and hemostasis of soft tissue -Treatment of wrinkles -Treatment of mild to moderate inflammatory acne vulgaris 532 nm wavelength in Q-switched mode (nominal delivered energy of 585 nm and 650 nm with the optional 585 nm and 650 nm dye converter handpieces): -Red, tan, purple and orange tattoo ink removal -Sky blue (light) tattoo ink removal -Green tattoo tattoo ink removal	1064nm in Genesis (long-pulse) mode: - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris 532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 595 nm and 660 nm with optional dye handpieces): - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of Lentigines - Treatment of Café-au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory	

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
	treatment of acne scars and wrinkles -Removal of epidermal pigmented lesions	-Treatment of benign pigmented lesions including, but not limited to: cafe-au-lait birthmarks, solar lentigines, senile lentigines, senile lentigines, Becker's nevi, freckles, common nevi, nevus spilus -Treatment of benign vascular lesion including, but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi -Seborrheic Keratosis -Treatment of post-inflammatory hyperpigmentation -Skin resurfacing procedures for the treatment of acne scars and wrinkles -Removal of epidermal pigmented lesions 532 nm wavelength in long pulse mode: -Incision, ablation vaporization, coagulation and hemostasis of vascular lesions and soft tissue in various surgical	Hyperpigmentation - Treatment of Becker's Nevi, Freckles, and Nevi spilus	

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
		areas. All soft tissue is included, such as skin, cutaneous tissue, subcutaneoous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. -The treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size) of the benign vascular lesions (Angiomas, Hemangiomas, Telangiectasia) 1064 nm wavelength in PICO mode: -Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple -Benign pigmented lesions removal for Fitzpatrick Skin Types I-IV -Treatment of acne scars in Fitzpatrick Skin Types II-V -Treatment of wrinkles as well as benign pigmented		

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
		lesions in Fitzpatrick Skin Types I-IV 532 nm wavelength in PICO mode: -Tattoo removal in Skin Types I - III -Treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV		
Laser Source	Nd:YAG	Nd:YAG	Nd:YAG	Identical
Wavelength	532/1064 nm 585/650 nm with dye convertible handpieces	532/1064 nm 585/650 nm with dye convertible handpieces	532/1064 nm 595/660 nm with dye convertible handpieces	Identical to predicate #1, equivalent to #2
Max. Fluence	**1064nm:** Single: 48.00 J/cm2 Genesis: 102.00 J/cm2 **532nm:** Single: 16.05 J/cm2	- Not disclosed in public documentation	**1064nm**: 48J/cm2 Genesis: 100J/cm2 **532nm**: 15J/cm2	Max. Fluence is equivalent to predicate #2
Pulse Energy	**1064nm**: Singe: Up to 1532 mJ PTP: Up to 2019 mJ 3Pulse: Up to 2521 mJ 6Pulse: Up to 3016 mJ Genesis: Up to 3299 mJ **532nm:** Single: Up to 509 mJ PTP: Up to 505 mJ	**1064nm:** Q-switched: Up to 1600 mJ Long-Pulsed: Up to 15000 mJ (long pulsed) PICO Nd:YAG: Up to 800 mJ **532nm:**	**1064nm:** 50 - 1,200 mJ PTP: 600 - 2,000 mJ Triple mode: 1,000 - 1400 mJ 2x PTP: 1,000 - 1400 mJ Genesis: 100 - 5,000 mJ **532 nm:** 30 - 500 mJ	**1064nm:** Single: less than predicate #1 PTP, multi-pulse, & genesis (long pulse): less than genesis for predicate #2 **532nm:** Within range of predicate #1

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
	585nm: Up to 252mJ **650nm:** Up to 153mJ	Q-switched: Up to 600 mJ Long-Pulsed: Up to 2000 mJ PICO KTP: Up to 300 mJ **585nm:** Not disclosed in public documentation **650nm:** Not disclosed in public documentation	**595 nm**: 30 - 250 mJ **660 nm**: 30 - 150 mJ	**585nm:** Equivalent to predicate #2 **650nm:** Equivalent to predicate #2
Pulse Width	**1064nm:** 5-10 ns (Single, PTP, 3 Pulses, 6 Pulses mode) 60-300 µs (Genesis) **532nm:** 5-10 ns (Single, PTP mode)	**1064nm:** 5 - 20 ns (Q-switched) 600 - 5000 µs (long pulsed) 300 - 400 ps (PICO Nd:YAG) **532nm:** 5 – 20 ns (Q-switched) 15-50ms (long pulsed) 300 - 400 ps (PICO KTP)	**1064nm:** 5 – 12 ns Up to 20ns (PTP/Triple/2X PTP): 80-300 µs (Genesis) **532nm:** 5 – 12 ns	**1064nm:** Equivalent to predicates #1 and #2 **532nm:** Equivalent to predicates #1 and #2
Max. Repetition Rate (Hz)	**1064nm** 15 Hz (all modes) **532nm** 10 Hz (all modes)	**1064nm** 0.5 - 15 Hz (Q-switched) 0.5 - 10 Hz (PICO Nd:YAG) **532nm** 0.5 - 10 Hz (Q-switched)	**1064nm** 1 - 10 Hz (all modes) **532 nm** 1 - 10 Hz	**1064nm:** Equivalent to predicate #1 **532nm:** Equivalent to predicates #1 and #2

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
	585nm 1 Hz (all modes) **650nm** 1 Hz (all modes)	0.5 - 1 Hz (long pulsed) 0.5 - 8 Hz (PICO KTP)	**595 nm** 1 - 5 Hz **660 nm** 1 - 2 Hz	**585nm:** Equivalent to predicate #2 **650nm:** Equivalent to predicate #2
Spot Size	**Zoom**: 2-10 mm **Collimation**: 8 mm **MLA**: 4-9mm **Dye**: 3mm	- Not disclosed in public documentation	**Zoom**: 2-10mm **Collimation**: 7mm **MLA**: 3-8mm **Dye**: 3mm **DOE**: 5mm x 5mm ~ 7mm x 7mm	Spot Size is similar to predicate #2

8. Non-Clinical Test Summary

The 'BELLUS-Q' complies with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The 'BELLUS-Q' complies with the electrical safety and electromagnetic compatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
60601-1	IEC	Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance	3.2	2020
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	4.1	2020
60601-2-22	IEC	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	4.0	2019
60825-1	IEC	Safety of laser products – Part 1: Equipment classification and requirements	3.0	2014

2) Biocompatibility Testing

The 'BELLUS-Q' complies with the bio-compatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
10993-5	ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	3.0	2009
10993-10	ISO	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	4.0	2021
10993-23	ISO	Biological evaluation of medical devices - Part 23: Tests for irritation	1.0	2021

3) Software Validation

The 'BELLUS-Q' contains Enhanced Documentation Level software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for software contained in medical devices, on June 14, 2023

4) Bench Testing

Bench testing of the laser output energy, wavelength, repetition rate, spot size, pulse width, and beam output was conducted to verify the device's performance and to demonstrate that it achieves its claimed performance. These results support the demonstration of substantial equivalence to the predicate device.

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between the proposed device and the predicate devices K202172 and K241527 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

10. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the 'BELLUS-Q' is substantially equivalent in safety and effectiveness to the predicate devices as described herein.