October 10, 2024

Quanta System S.p.A.
Dario Bandiera
Regulatory Affairs Manager
Via Acquedotto 109
Samarate, VA 21017
Italy

Re: K241092
Trade/Device Name: Youlaser PRIME; Youlaser PRIME CO2; Youlaser PRIME MT
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 12, 2024
Received: September 12, 2024

Dear Dario Bandiera:

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2024.10.10 23:28:14 -04'00'

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.

Submission Number *(if known)*

K241092

Device Name

Youlaser PRIME;
Youlaser PRIME CO2;
Youlaser PRIME MT

Indications for Use *(Describe)*

The Youlaser PRIME family laser devices (Youlaser PRIME, Youlaser PRIME CO2, Youlaser PRIME MT) and accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery).

Surgical Handpieces

Youlaser PRIME CO2, Youlaser PRIME and Youlaser PRIME MT with a wavelength of 10600nm used in combination with surgical handpieces are indicated for use for the particular indications as follows:

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- laser skin resurfacing
- laser derm-abrasion
- laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts.

OptiScan PRIME Scanner

Youlaser PRIME CO2, Youlaser PRIME and Youlaser PRIME MT with a wavelength of 10600nm used in combination with OptiScan PRIME scanner are indicated for:

- Laser skin resurfacing (ablation and/or vaporization) of soft tissue

Youlaser PRIME and Youlaser PRIME MT with wavelength of 1550nm used in combination with OptiScan PRIME scanner, are indicated for:

- Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue

Youlaser PRIME MT with wavelengths of 10600nm & 1550nm used in combination with OptiScan PRIME is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.

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

K241092

Applicant / Manufacturer and address:	Quanta System S.p.A., Via Acquedotto 109, 21017 Samarate (VA), Italy
Contact person:	Dario Bandiera RA Manager Quanta System S.p.A. Email: dario.bandiera@quantasystem.com Phone: +39-0331-376797
Date Prepared:	03/10/2024
Trade/device name:	Youlaser PRIME, Youlaser PRIME CO2, Youlaser PRIME MT
Classification:	Class II
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Predicate devices:	The Alma Hybrid Laser System (K203441), Deka Helix (K222221), Youlaser CO2 (K182669)

1 Abbreviations

FW= firmware
GUI= graphical user interface
SW= software

2 Device description

The models of the Youlaser PRIME family are medical laser emitting at 10600nm (CO2 laser source), 1550nm, plus combined configurations.
The 1550nm laser source is a fiber laser, this wavelength lies in the invisible infrared part of the electromagnetic spectrum.
The CO2 laser source is an RF driven sealed gas tube emitting laser radiation both in continuous and pulsed mode in the invisible far-infrared part of the electromagnetic spectrum (10600nm).
The beam delivery system is an articulated arm with a handpiece or a scanner on its end.
The laser device is equipped with a display with a graphical user interface (GUI) for user-device interaction (e.g. laser parameters settings).
The scanner is also provided with a touchscreen display to select the scan pattern, shape, dimension,…etc.
Laser emission is controlled via the external footswitch. The footswitch has an activation pedal which enables laser emission.

3 Comparison with the predicate

In Table 1, the main specifications of the subject device are summarized and compared to the predicates:

Table 1: Main specifications comparison table.

Specification	Subject Device	Predicate 1	Predicate 2	Predicate 3	Comments
Device Name	*Youlaser PRIME MT, Youlaser PRIME, Youlaser PRIME CO2*	*The Alma Hybrid Laser System*	*Deka Helix*	*Youlaser CO2*	
(K number)	**K241092**	**K203441**	**K222221**	**K182669**	**--**
Manufacturer	Quanta System S.p.A.	Alma Lasers, Ltd.	El.En Electronic Engineering Spa	Quanta System S.p.A.	--
Product Code	GEX	GEX, ONG	GEX, ONG	GEX	Identical
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
Laser Classification	II	II	II	II	Identical
User Interface	Touch-screen display Emergency Button Key Switch	Touch-screen display Emergency Button Key Switch	Touch-screen display Emergency Button Key Switch	Touch-screen display Emergency Button Key Switch	Identical
Laser Wavelength	10.6 µm ± 0.4µm 1550nm ± 1nm	10.6 µm 1570nm	10.6 µm ± 0.4µm 1570nm ± 10nm	10.6 µm ± 0.4µm	Discussion 1
Power	Up to 50W @10600nm Up to 15W @1550nm	Up to 70W @10600nm Up to 15W @1570nm	Up to 70W @10600nm Up to 14.4W @1570nm	Up to 30W @10600nm	Within the range of predicate devices
Aiming beam	630 – 650 nm, <5mW, Class 3R	650nm, 3mW	635nm, 4mW	650nm, < 4 mW, Class 3R	Within the range of the predicate devices

Emission Control	Footswitch Interlock	Footswitch Interlock	Footswitch Interlock	Footswitch Interlock	Identical
Delivery devices	Surgical Handpieces and scanner (OptiScan PRIME)	Handpieces and scanner (HyLight Applicators, Pixel Applicators, ProScan)	Handpieces and scanner (CO2 handpieces, CO2/1570nm Scanning unit)	Surgical Handpieces and scanner (OptiScan)	Differences do not affect safety and effectiveness
Beam delivery System	Articulated arm	Articulated arm	Articulated arm	Articulated arm	Identical
Power Supply	100-240 VAC, 50/60 Hz	120 VAC, 11 A, 50/60 Hz, single phase 220/230 VAC, 6 A, 50/60 Hz, single phase	100-230 V, 16A 50/60 Hz	115 Vac; 50/60 Hz or 230 Vac; 50/60 Hz	Differences do not affect safety and effectiveness
Dimensions	564x570x1252 mm (erected)	465x533x1345/1973mm (erected)	620x630x1380/1020 mm (erected)	580x460x 1330 mm (erected)	Differences do not affect safety and effectiveness
Weight	130Kg	86Kg	70Kg	55Kg	Differences do not affect safety and effectiveness
Part in contact with patient - Material	Stainless Steel AISI 316L	Data not available	Data not available	Stainless Steel AISI 316L	Identical
Handpieces – Non fractional					
Spot Size (mm)	Surgical Handpieces • 0.150 – 2 mm	HyLight CO2 • 0.15 – 3 mm @50mm working distance • 0.25 – 3.1 mm @200mm working distance	CO2 Handpieces • 0.125 – 2.0 mm	Surgical Handpieces • 0.200 – 1 mm	Within the range of the predicate devices
Frequency	@10600nm 0.5-200 Hz: Up to 50W 0.5-995 Hz/CW: Up to 30W	1-100 Hz @10600nm	0.2 – 200 Hz @10600nm	@10600nm Up to 1000 Hz /CW	Within the range of the predicate devices.
Pulse Duration	5µs-1000ms @10600nm	1-1000ms @10600nm	10 - 900ms @10600nm	up to 80ms @10600nm	Differences do not affect safety and effectiveness
Fluence	Max 2830 J/mm2 @50W	Max 3530 J/mm2 @70W			Within the range of the predicate device
Scanning Unit - Fractional					
Spot Size	OptiScan PRIME @10600nm and @1550nm: Spot size: 0.250mm Scan size: up to 18x18mm	ProScan CO2 spot size @10600nm: 0.35mm @100 mm distance ProScan 1570 spot size @1570nm: 0.75mm scan size @1570nm: Up to 30 mm diameter	Scanning Unit spot size @10600nm: 0.374mm spot size @1570nm: 0.75mm scan size @1570nm: 20x20mm	Optiscan Spot size @10600nm: 0.300mm Scan size: up to 18x18mm	Differences do not affect safety and effectiveness: Discussion 2
Max Output Energy	@10600nm: 122mJ @1550nm: 80mJ	@10600nm: 240 mJ @1570 nm: 144 mJ/pixel	@10600nm: 251mJ @1570 nm: 144mJ	@10600nm: 60mJ	Discussion 2

	@mixed emission 10600nm+1550nm: 75mJ + 80mJ				
frequency	Up to 1Hz	Data not available	Data not available	Data not available	According to our in vivo study: Discussion 2
Beam Density @10600nm	80% - 98% untreated tissue between spots Up to 400 (dot/cm2)	~63% - 97% untreated tissue between spots	61% - 98% untreated tissue between spots	Up to 400 (dot/cm2)	Same of predicate Youlaser CO2. Safer condition for untreated tissue: Discussion 2
Beam Density @1550 nm	80% - 98% untreated tissue between spots Up to 400 (dot/cm2)	Up to 390 pixels/cm2	Up to 400 pixels/cm2	-	Same of predicate Deka Helix. Safer condition for untreated tissue: Discussion 2
Intended Use					
Intended Use	The Youlaser PRIME family laser devices (Youlaser PRIME, Youlaser PRIME CO2, Youlaser PRIME MT) and accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery). Surgical Handpieces Youlaser PRIME CO2, Youlaser PRIME and Youlaser PRIME MT with a wavelength of 10600nm used in combination with surgical handpieces are indicated for use for the particular indications as follows: Dermatology & Plastic Surgery The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of: * laser skin resurfacing	The Alma Hybrid Laser System, Delivery Devices, Applicators and Accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery). HyLight-CO2 The Alma Hybrid CO2 non-fractional applicator, with wavelength of 10600 nm is cleared for use for the particular indications as follows: Dermatology & Plastic Surgery The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of: *laser skin resurfacing *laser derm-abrasion *laser burn debridement. Laser skin resurfacing (ablation and/or	The Helix Laser System with its accessories is intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery). CO2 Handpieces The Helix CO2 handpieces with wavelength of 10600 nm are indicated for use for the particular indications as follows: Dermatology & Plastic Surgery The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of: * laser skin resurfacing * laser derm-abrasion * laser burn debridement. Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or	YOULASER CO2 laser when used in traditional, non-fractionated mode for: Incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otorhinolaryngology (ENT), gynaecology, neurosurgery, dental and oral surgery and genitourinary surgery. YOULASER CO2 laser when used in fractionated mode (scanner) is indicated only for ablative skin resurfacing.	Same of Alma Hybrid and Deka Helix.

	* laser derm-abrasion * laser burn debridement. Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts. OptiScan Scanner Youlaser PRIME CO2, Youlaser PRIME and Youlaser PRIME MT with a wavelength of 10600nm used in combination with OptiScan PRIME scanner are indicated for: •Laser skin resurfacing (ablation and/or vaporization) of soft tissue Youlaser PRIME and Youlaser PRIME MT with wavelength of 1550nm used in combination with OptiScan PRIME scanner, are indicated for: • Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue Youlaser PRIME MT with wavelengths of 10600nm & 1550nm used in combination with OptiScan PRIME is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.	vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts. Pixel The Alma Hybrid Pixel CO2 fractional applicator, with wavelength of 10600 nm is indicated for: The ablation, vaporization, and coagulation of soft tissue in dermatology and plastic surgery in the performance of skin resurfacing. ProScan The Alma Hybrid ProScan CO2 fractional applicator, with wavelength of 10600 nm is indicated for: •Laser skin resurfacing (ablation and/or vaporization) of soft tissue. The Alma Hybrid ProScan 1570nm fractional applicator, with wavelength of 1570 nm, is indicated for: •Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue The Alma Hybrid ProScan CO2 &1570nm fractional applicator, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.	treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts. Scanning unit The Helix Scanning unit, with wavelength of 10600 nm is indicated for: •Laser skin resurfacing (ablation and/or vaporization) of soft tissue The Helix Scanning unit, with wavelength of 1570 nm, is indicated for: • Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue The Helix Scanning unit, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.		

Discussion 1

The laser wavelength of this device is similar to K203441 and K222221.

According to the laser absorption curve of human tissues, the wavelength range from 1500nm to 1600nm belongs to the main absorption of water, while absorption by other components is minimum. Therefore, the subtle wavelength difference between 1550nm and 1570nm will not have any difference in the penetration depth of laser and the absorption effect of tissues, and will not affect the clinical effectiveness.

Discussion 2

The Youlaser PRIME family devices integrate a CO2 laser source at 10600nm and a fiber laser source at 1550nm, both of which are analyzed in terms of their safety and efficacy for clinical skin treatments. The

accessory OptiScan is used in combination with the device for delivering the laser radiation to the patient. It receives the laser radiation from the laser device (CO2, Erbium Fiber Laser or mixed) as a uniform spot and delivers it to the skin tissue in the form of patterns of different shape and dimension. The fractional grid patterns are substantially equivalent to the predicate devices with differences regarding spot size and beam density.
Despite these differences, the maximum energy level for the 10600nm source, which is limited to 122mJ, when compared to the stated spot size, ensures an equal fluence level between the compared devices. Since the depth of ablation is directly related to the energy levels delivered, the safety of the treatment in terms of depth of ablation and extent of thermal damage can be considered comparable.

Another key aspect is the micro spot density setting, which is limited to 400 dots/cm². This spot density value generates a pattern of ablative and thermal lesions with a pitch of approximately 500µm, but with a wider distance respect to the predicates. This configuration results in a pattern of ablative and thermal lesions that leave untreated skin between the treated areas, promoting faster healing and minimizing discomfort.

The Fiber Laser Source (1550nm) follows a similar strategy, with a maximum energy level of 80mJ, verified through in vivo testing on minipigs.
Testing was performed safely on the test animals, and the histology results complied with the FDA requirements, from 0 to 14 days. Three animals were used in this study.
Re-epithelization was observed three days after radiation in all specimens. Slight erythema was noted as the primary side effect in higher energy settings, but it was transient and resolved within days. No cases of oedema were observed, and overall, the healing process was uncomplicated.
Histologic analysis performed with H&E staining at various time points (days 1, 4, and 14) revealed predictable levels of ablation and coagulation depending on the energy settings used, with the fiber laser causing predominantly coagulation while the CO2 laser focused on ablation. By day 4, re-epithelialization of the skin was already evident, and by day 14, the skin had fully healed.
The Youlaser PRIME device demonstrates predictable and controlled skin ablation and coagulation, ensuring patient safety and clinical efficacy.

The findings confirm that the device is equivalent to other approved technologies, with precise control over energy output and microspot density to facilitate rapid healing and minimize side effects.

4 Indication for use

The Youlaser PRIME family laser devices (Youlaser PRIME, Youlaser PRIME CO2, Youlaser PRIME MT) and accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery).

Surgical Handpieces
Youlaser PRIME CO2, Youlaser PRIME and Youlaser PRIME MT with a wavelength of 10600nm used in combination with surgical handpieces are indicated for use for the particular indications as follows:

Dermatology & Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- laser skin resurfacing
- laser derm-abrasion
- laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts.

OptiScan PRIME Scanner
Youlaser PRIME CO2, Youlaser PRIME and Youlaser PRIME MT with a wavelength of 10600nm used in combination with OptiScan PRIME scanner are indicated for:
•Laser skin resurfacing (ablation and/or vaporization) of soft tissue

Youlaser PRIME and Youlaser PRIME MT with wavelength of 1550nm used in combination with OptiScan PRIME scanner, are indicated for:
• Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue

Youlaser PRIME MT with wavelengths of 10600nm & 1550nm used in combination with OptiScan PRIME is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.

5 Non-clinical tests

The present device was subject to non-clinical testing according to the following standards (Table 2):

Table 2: Applied standards.

Standard
IEC 60601-1:2005/AC 1:2006/A1:2012/AC1:2014/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014; IEC 60601-1-2:2014/A1:2020 Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6: 2010/AMD1: 2013 Collateral standard: Usability
IEC 62366-1: 2015/COR1: 2016 Part 1: Application of usability engineering to medical devices
IEC 62304: 2006/AMD1: 2015 Medical device software (SW)
IEC 60601-2-22: 2019 Particular requirements for basic safety and essential performance of surgical, cosmetic etc.
IEC 60825-1: 2014 Safety of laser products – Part 1: Equipment classification and requirements
ISO 10993-1: 2018 Biological evaluation of medical devices

In addition, in vivo testing on minipigs and histological analysis were performed to demonstrate safety and effectiveness of the Fiber Laser Source (1550nm), with a maximum energy level of 80mJ. Testing was performed safely on the test animals, and the histology results complied with the FDA requirements, from 0 to 14 days. Three animals were used in this study.

The results of the non-clinical performance testing support that the subject device can be used safely and effectively.

6 Substantial equivalence discussion

Youlaser PRIME family devices have the same intended use of the predicate devices and comparable technical specifications.

7 Conclusions

Non-clinical tests conducted support that the devices can be used safely and effectively for the proposed indications for use. The differences in technological characteristics between the subject and predicate devices do not raise new questions regarding safety and effectiveness for the proposed indications for use. Thus, the subject device is considered to be substantially equivalent to the predicate devices.