Quanta System SpA
Francesco Dell'antonio
Vice President, Regulatory Affairs and QA
Via Acquedotto 109
Samarate, 21017 It

October 17, 2018

Re: K182669
Trade/Device Name: Youlaser CO2
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 10, 2018
Received: September 25, 2018

Dear Francesco Dell'antonio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 located 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S
2018.10.17 08:47:17 -04'00'

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182669

Device Name
Youlaser CO2

Indications for Use *(Describe)*

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.

When used in fractionated mode (scanner), it is indicated only for ablative skin resurfacing.

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.

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"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."

5. 510(K) SUMMARY

Applicant / Manufacturer Name and Address:	Quanta System SPA Via Acquedotto, 109 21017 Samarate (VA) Italy
510(k) Contact Person:	Francesco Dell'Antonio Vice President Regulatory Affairs and QA Quanta System SpA Email: francesco.dellantonio@quantasystem.com Phone: +39-0331-376797 Fax: +39-0331-367815
Date Prepared:	16th October 2018
Brand Names:	Youlaser CO2
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
Basis for Submission:	Device modifications
Primary Predicate Device:	Youlaser CO2 (K123573) – Quanta System SpA

Performance Standards:

There are no mandatory performance standards for this device.

Device description

YOULASER CO2 laser device has a CO2 laser source emitting at 10600 nm. The beam delivery is enabled through an articulated arm.
Emission is triggered by means of the footswitch or the finger switch available on the scanner.

Description of the modifications:

This Special 510(k) is submitted due to techcnial modifications of the already cleared device.

The device was changed as follows:

- Electronics: an embdedded PC is added to manage the GUI
- A prioprietary Scanner – Optiscan – is introduced
- Emission is triggered also from a fingerswitch mounted on the scanner
- Change to the GUI appearance
- Change to the external panels

Based on the nature of the changes implemented, the device underwent and successfully passed electrical safety, EMC, performance testing and software verifications and validation according to the relevant standards.

Intended Use/Indications for Use

The subject device has the same intended use of the unmodified device, as follows:

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.

When used in fractionated mode (scanner), it is indicated only for ablative skin resurfacing.

Performace testing

The subject device underwent performance testing in accordance with the following recognized consensus standards related to electromagnetic compatibility, electrical safety and performances:

- IEC 60601-1:2005 + AMD1:2012 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 + AMD1:2012, Medical Electrical Equipment - Part 2-22: Particular requirements for basic 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

The subject device passed all the required testing and complies with all applicable sections of the above-mentioned standards.

Comparison with predicate device:

The subject and unmodified devices have the same intended use and the same fundamental scientific technology, based on Co2 laser sources, with equivalent specifications.

Summary

The subject device is substantially equivalent to its identified predicate device.