October 15, 2020

Quanta System SpA
Francesco Dell'Antonio
Vice President Regulatory Affairs and QA
Via Acquedotto 109
Samarate, Varese 21017
Italy

Re: K202041
Trade/Device Name: Opera Evo
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: July 20, 2020
Received: July 23, 2020

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/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 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 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,

Purva Pandya
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K202041

Device Name
Opera Evo

Indications for Use *(Describe)*
Opera Evo laser device and its fibre optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical Traditionalties including: Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, General Surgery and Arthroscopy.

Urology:
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
• Urethral Strictures
• Bladder Neck Incisions (BNI)
• Ablation and Resection of Bladder Tumors, Urethral and Ureteral Tumors
• Ablation of Benign Prostatic Hypertrophy (BPH)
• Transurethral Incision of the Prostate (TUIP)
• Laser Resection of the Prostate
• Laser Enucleation of the Prostate
• Laser Ablation of the Prostate
• Condylomas
• Lesions of external genitalia

ENT:
Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:
• Endonasal/sinus Surgery
• Partial turbinectomy
• Polypectomy
• Dacryocystorhinostomy
• Frontal sinusotomy
• Ethmoidectomy
• Maxillary antrostomy
• Functionale endoscopic sinus surgery
• Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal area
• Tonsillectomy
• Adenoidectomy

Gastroenterology:
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
• Polyps
• Biopsy
• Gall Bladder calculi
• Biliary/Bile duct calculi
• Ulcers
• Gastric ulcers
• Duodenal ulcers

• Non-bleeding ulcers
• Pancreatitis
• Hemorrhoids
• Cholecystectomy
• Benign and Malignant Neoplasm
• Angiodysplasia
• Colorectal cancer
• Telangiectasias
• Telangiectasias of the Osler-Weber-Rendu disease (OWRD)
• Vascular Malformation
• Gastritis
• Esophagitis
• Esophageal ulcers
• Varices
• Colitis
• Mallory-Weiss tear
• Gastric erosion

Thoracic and Pulmonary
Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue including:
• Laryngeal lesions

Gynecology:
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
• Intra-uterine treatment of submucous fibroids
• Benign endometrial polyps and uterine septum by incision, excision, ablation and vessel coagulation
• Soft tissue excision procedures such as excisional conization of the cervix

General Surgery:
Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:
• Cholecystectomy
• Lysis of adhesion
• Appendectomy
• Biopsy
• Skin incision
• Tissue dissection
• Excision of external tumors and lesions
• Complete or partial resection of internal organs, tumors and lesions
• Mastectomy
• Hepatectomy
• Pancreatectomy
• Splenectomy
• Thyroidectomy
• Parathyroidectomy
• Herniorrhaphy
• Tonsillectomy
• Lymphadenectomy
• Partial Nephrectomy
• Pilonidal Cystectomy
• Resection of lipoma
• Debridement of Decubitus Ulcer

• Hemorrhoids
• Debridement of Statis Ulcer

Arthroscopy:
Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)
Ablation of soft, cartilaginous and bony tissue in Minimal invasive Spinal Surgery including:
• Percutaneous Laser Disc Decompression/Discectomy
• Foraminoplasty
• Ablation and coagulation of soft vascular and nonvascular tissue in minimally invasi ve spinal surgery

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 Samarate (VA) Italy, 21017
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:	June 30th 2020
Device Name:	Opera Evo
Common name:	Surgical laser
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 Device	MultiPulse TM+1470 – Asclepion Laser Technologies Gmbh (K133891)

Description of the device:

The Opera Evo laser device includes a diode laser that emits a wavelength of 1940 nm and includes a diode laser that emits a wavelength of 1470 nm, with a combined cumulated laser output power up to 40W. Laser radiation is delivered to the patient via a quartz optical fiber having a diameter up to 1000 µm.
The main subsystems of the device are the two diode lasers, the power electronics, the optical delivery system, the control electronics, and the cooling system. Software controls the device functions and allows the user select device settings. Laser emission is triggered by a footswitch

Summary of the technological characteristics

	Subject device	Predicate device(s)	Comparison to predicate devices
model name	Opera Evo	MultiPulse TM+1470	-
manufacturer	Quanta System SpA	Asclepion Laser Technologies Gmbh	-
510(k)	-	K133891	-
Laser Source	diode lasers	Thulium:YAG laser and diode laser	The differences in technology result in the same laser output parameters range
Wavelength (nm)	1.94 µm and 1.47 µm	1.94 µm and 1.47 µm	Same as
Emission	CW/pulsed	CW/pulsed	Same as
Pulse duration	1 ms up to CW	0.5 ms up to CW	Within the range of the predicate
Frequency	Up to 250 Hz	Up to 1000 Hz	Within the range of the predicate
Max average power	40 W	150 W	Within the range of the predicate
Delivery system	Optical fibers	Optical fibers	Same as
Aiming beam	520nm laser < 5 mW	635nm laser < 5 mW	Equivalent

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- Telangiectasias of the Osler-Weber-Rendu disease (OWRD)
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- Parathyroidectomy
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- Foraminoplasty
- Ablation and coagulation of soft vascular and nonvascular tissue in minimally invasi ve spinal surgery

Accessories

This device is intended to be used together with delivery optical fiber that separately received a FDA clearance for an intended use compatible with the one of this device.

Performance testing

The subject device was subject to testing according to the following recognized consensus standards related to electromagnetic compatibility, electrical safety and performances.

- IEC 60601-1:2012, ed 3.1, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety And Essential Performance

- IEC 60601-1-2:2014, ed 4, 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: 2012, ed 3.1, 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, ed 3.0, Safety of laser products – Part 1: Equipment classification and requirements

- IEC60601-1-6:2013, ed 3.1, Medical Electrical Equipment Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability

- Software Verification and Validation Testing: Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

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

Comparison with predicate device:

The subject device's technological characteristics and indications for use are similar to the predicate device, and its laser output ranges are within the those of the predicate device. Other differences between the subject and predicate device to not raise new types of questions regarding the subject

device's safety and efficacy.

Conclusions

The non-clinical performance testing conducted supports that the device can be used safely and effectively. The differences in the indications for use and technological characteristics between the subject and predicate device do not raise new types of questions regarding safety and effectiveness, and the subject device is considered substantially equivalent to the predicate device.