November 18, 2022

SQUALUS MED Ltd.
Gil Shapira
CEO
7 HaEshel Street
Caesarea, 3088900
Israel

Re: K222701
Trade/Device Name: MANTA Laser
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: August 31, 2022
Received: September 7, 2022

Dear Gil Shapira:

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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222701

Device Name
MANTA Diode Lasers

Indications for Use *(Describe)*
The MANTA810 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The MANTA980 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The MANTA1064 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The MANTA1470 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The MANTA1940 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

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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K222701

MANTA Laser Family

Submitter:	SQUALUS MED Ltd. 7 HaEshel Street, Caesarea 3088900 Israel
Contact person:	Gil Shapira, CEO
Phone:	+972 4 6779919
Fax:	+972 4 8591505
E-Mail:	shapirag@squalusmed.com
Type of 510(k):	Traditional
Date Prepared:	August 28, 2022
Device Trade name	MANTA Diode Laser Family
Common name	Diode Laser System
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Device product code:	GEX
Device Classification	21 CFR 878.4810
Predicate Devices:	Quanta Diode Laser Family (K100558)

Device Description:
The MANTA diode lasers are a family of products with a laser diode as the beam source. Dependent on the chosen diode, the laser system can radiate one factory set wavelength with any of the following: 810nm, 980nm, 1064nm, 1470nm or 1940nm.
The MANTA is a compact diode laser with a high-resolution color touchscreen for user control.

Indications for Use:
The Indications for use are a subset of the Indications for Use of the predicate device. There is no change in content of the Indications for Use claimed for the MANTA Diode Laser Family, or addition of any new indications.

The MANTA810 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The MANTA980 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The MANTA1064 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The MANTA1470 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

The MANTA1940 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.

Substantial Equivalence

Specification	**Subject device**	**Predicate Device**	**Substantial Equivalence**
510(k) Number	Pending	K100558	
Manufacturer	SQUALUS MED Ltd.	Quanta System S.p.a	
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Equivalent
Product Code	GEX	GEX	Equivalent
Regulatory Class	Class II	Class II	Equivalent
Indications for Use	The MANTA810 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures. The MANTA980 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in	The Quanta System Quanta Diode Laser Family, including the QUANTA532, QUANTA808, QUANTA940, QUANTA1064, QUANTA1320, QUANTA1470, and QUANTA1950 (and all their double wavelength combination and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures. ***Page 5-3***	

	conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures. The MANTA1064 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures. The MANTA1470 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery,		

	Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures. The MANTA1940 diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures.		
Laser media	Diode laser	Diode laser	Equivalent
Use of device	RX only	RX only	Equivalent
Max. power (Watts)	28 – 810nm 28 – 980nm 24 – 1064nm 12 – 1470nm 5 – 1940nm	30 – 808nm 30 – 980nm 30 – 1064nm 15 – 1470nm 5 - 1950	Equivalent (see conclusion on page 5-X)
Wavelength (nm)	810, 980, 1064, 1470, 1940	808, 980, 1064, 1470, 1950	Equivalent (see conclusion on page 5-7)
Laser class	4	4	Equivalent
Output Mode	CW, pulsed, single pulse	CW, pulsed, single pulse	Equivalent
			Page 5-5

Pulse Duration	10 msec – 30 sec adjustable	3 msec – 2.5 sec adjustable	Equivalent See conclusion on page 5-7)
Pulse frequency	0.02 – 50 Hz	0.016 – 250 Hz	Equivalent See conclusion on page 5-7)
Aiming Beam	Red 635-650nm (<5mW)	Red 650nm (<5mW)	Equivalent
Cooling	Air	Air	Equivalent
Laser Beam Delivery	Fiber	Fiber	Equivalent
User Interface	Color touch screen	Color touch screen	Equivalent
Power Source	100 – 240 V, 47-63 Hz	100-240V, 50-60Hz	Equivalent
Dimensions & Weight	22 cm (L) x 22 cm (W)x 10 cm (H) 3.5 Kg.	39 cm (L) x 33 cm (W) x 25 cm (H) 8 Kg.	Equivalent

Performance testing

The MANTA systems have been tested against:

Number of Standard	Name of Standard
IEC 60601-1:2005+ COR1:2006, COR2:2007, AMD1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
IEC 60825-1:2014 (Third Edition)	Safety of Laser Products – Part 1: Equipment classification and requirements
EN 60601-1-2:2014 (Forth Edition)	Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests.
IEC 60601-2-22:2007 (Third Ed.) +A1:2012 for use in conjunction with IEC 60601-1:2005 (Third Ed.) + A1:2012	Medical electrical equipment Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-1-6:2010/ AMD1:2013 & IEC 60601-1:2005, AMD1:2012, AMD2:2020	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62304:2006 + A1:2015	Medical device software – Software life cycle process

Substantial Equivalence summary and conclusion Substantial equivalence between the subject device and the predicate device has been evaluated. The minor differences in design/operation are only a question of usability and do not play a role in safety or effectiveness as the fundamental functions and the indications for use are the same.

Animal or clinical studies: None