InnovaQuartz LLC
Stephen Griffin
Chief Innovations Officer
23030 N 15th Avenue
Phoenix, Arizona 85027-1315

Re: K233157
Trade/Device Name: VaporMAX LDD; MOJo LDD; MegaJOULE LDD
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: April 2, 2024
Received: April 3, 2024

Dear Stephen Griffin:

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.

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: 2024.05.03 21:53:12 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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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.

510(k) Number *(if known)*
K233157

Device Name
VaporMAX LDD, MegaJOULE LDD, and MoJo LDD

Indications for Use *(Describe)*
The VaporMax LDD® family of laser fibers, which includes VaporMAX LDD, MegaJOULE LDD and MoJO LDD, are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500 nm and 2200 nm have received regulatory clearance. The VaporMAX LDD family of laser delivery fibers are intended for use with any cleared surgical laser having a SMA 905 connector, SMA 906 connector or manufacturer specific connectors and adaptors.

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.

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510(K) Summary
K233157

Date Submitted: May 2, 2024

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Sponsor/Owner/Holder:
InnovaQuartz, LLC
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623-434-1895

Company Contact:
Stephen Griffin, CIO
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steveg@innovaquartz.com

Registration Number: 3010933841

Subject Device Name:

Trade Name:	VaporMAX LDD®, MegaJOULE LDD, and MoJo LDD
Common Name:	Laser Fiber
Classification:	Laser Instrument, Surgical, Powered Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	GEX
Regulatory Class:	Class II
Panel:	General and Plastic Surgery

Predicate Devices:

Trade Name:	VaporMAX™
Common Name:	Laser Fiber
Classification:	Laser Instrument, Surgical, Powered Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	GEX
Regulatory Class:	Class II
Panel:	General and Plastic Surgery
510(k) Number:	K053457 issued to Trimedyne, Inc., 15091 Bake Parkway, Irvine, CA 92618

Trade Name:	Multiwavelength Lateral Emitting Laser Fiber
Common Name:	Laser Fiber
Classification:	Laser Instrument, Surgical, Powered Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	GEX
Product Class:	Class II
Panel:	General and Plastic Surgery
510(k) Number:	K170366 issued to Laser Peripherals, LLC 13355 10th Ave, Ste 110, Plymouth, MN 55441

This statement is based on the similarity of the subject device to the predicate devices in the intended use and optical principles.

Device Description:

VaporMAX LDD® family of fibers, which includes VaporMAX LDD®, MegaJOULE LDD, and MoJo LDD, are fiber optic surgical laser energy delivery devices consisting of a stainless steel laser connector, e.g. SMA 905 or Trimedyne OmniPulse™ MAX, an anodized aluminum extension sleeve or polymer over-nut for accommodating recessed laser ports, fiber/connector strain relief, and a transmitting optical fiber consisting of a low [OH-], fused silica core fiber with fluorine-doped, fused silica cladding, a fluoropolymer secondary cladding and an ethylene tetrafluorethylene copolymer (ETFE, e.g. DuPont Tefzel 210™) protective jacket. The distal tip is laser polished and is disposed within a fused quartz capsule (cap) containing a beam conditioning lens and a prism for redirecting the output at nearly right angles to the fiber longitudinal axis.

The dimensional difference between the optical fiber and the distal cap is equalized with a Udel tube covering the distal length of fiber that may be tasked to pass a cystoscope bridge working channel, sized to match the cap diameter and upon which is dispose a green visual indicator of the fiber rotational orientation. The proximal end of the diameter matching tube is terminated within a patent pending control knob for ergonomic rotational control (aiming). Some models of the VaporMAX LDD, those with subscripted "e", where e" indicates "ergonomic") exploit severing the connection between the redirection prism from the transmitting fiber by providing for free rotation of the cap about the fiber, vial the control knob, thereby aiming the fiber output without torquing the transmitting fiber.

VaporMAX LDD fibers are packaged as a coil upon a coated fiberboard or dense polymer carrier card that is intended to provide for ease of dispensing within the surgical field while immobilizing the product within the sterile pouch. The working end (distal section) of the fiber is maintained in a straight configuration to avoid "fiber jumping" when rotated in surgery (due to the device's "memory" of being stored in a coil). Carrier cards are sealed within non-woven/impermeable polymer sterile pouches, e.g., Tyvek/paper or Tyvek/Mylar, currently validated by IQ for a three-year shelf life. Sealed sterile pouches are protected by an outer, nonsterile fiberboard carton. Both the sterile pouch and carton are labeled with the product information per FDA labeling requirements. All tissue contacting VaporMAX LDD materials of construction, and any materials in fluidic communication with tissue, are USP Class VI biocompatible and are compatible with ethylene oxide (EO) sterilization.

Intended Use:

The VaporMax LDD® family of laser fibers, which includes VaporMAX LDD®, MegaJOULE LDD, and MoJo LDD, are indicated for use in all surgical specialties in which compatible laser systems with operational wavelengths between 500 nm and 2200 nm have received regulatory clearance. The VaporMAX LDD family of laser delivery fibers are intended for use with any cleared surgical laser having a SMA 905 connector, SMA 906 connector or manufacturer specific connectors and adaptors.

Technological Characteristics Comparison:

The VaporMAX LDD laser fiber is produced as described in US Patents Nos. 9,323,005, 9,488,782 and patents pending. The subject fibers are technologically equivalent to the predicate devices and the intended end use for the subject fibers is the same as the intended use of the predicate devices. All the predicate devices and VaporMAX LDD operate upon the same optical principles, although somewhat refined. The VaporMAX LDD uses similar materials of construction as the predicate devices and has equivalent or better performance than the predicate devices. Table 4-6 illustrated in the comparison between VaporMAX LDD and the two predicate devices in the traditional 510(k) submission.

Feature	VaporMAX™ Predicate	VaporMAX LDD® Subject	LP Side Fire Predicate
Theory of Operation	Total Internal Reflection	Total Internal Reflection	Total Internal Reflection
Fiber total length	3 meters	3 meters	3 meters
Fiber core (um)	430, 550 and 600	365, 550 and 660	365 and 550
Fiber core material	Low [OH] fused silica	Low [OH] fused silica	Low [OH] fused silica
Fiber CCDR	1.05 and 1.1	1.1	1.1
Fiber cladding	F-doped fused silica	F-doped fused silica	F-doped fused silica
Fiber buffer	Fluoroacrylate	Fluoroacrylate	Fluoroacrylate
Fiber jacketing	ETFE	ETFE	ETFE
Working length	35 cm to 41 cm	36 cm & 38 cm	Variable
Control device	Fixed polymer	Fixed polymer	Movable metal
Laser connector	SMA 905 + TMED	SMA 905 + TMED	SMA 905, 906 & Proprietary
Output angle	78° to 82°	82° to 88°	UNKNOWN
Divergence	12.7°max	12.7° max	UNKNOWN
Cap diameter (max)	2.2 mm	2.14 mm	UNKNOWN
Output area	>0.8 mm^2	>1.2 mm^2	UNKNOWN
OD	7.5 French	7.5 French	UNKNOWN
Max energy	4.0 joules	4.0 joules	UNKNOWN
Max power	100 watts	200 watts	UNKNOWN
Minimum lifetime	320,000 J	600,000 J	UNKNOWN

Figure 1: Table 4-6 Comparison Table

Performance Testing (Bench and User Evaluation):

Briefly, subject fibers were power tested in simulated surgery like the predicate, under saline and in contact with tissue phantoms, at 80 watts average power (4 joules, 20 Hz), using a CTH:YAG laser operating at 2080nm (often incorrectly identified as “holmium lasers at 2100nm”) for 320,000 joules delivered, and similarly tested in contact with tissue phantoms at 200 watts using a thulium fiber laser operating at 1940nm for 600,000 joules and 1,000,000 joules (or one megajoule). The subject fibers maintained the original operating characteristics far further into testing than did predicate devices and none of the subject fibers failed even under the most abusive test conditions*, leading to the adoption of the new product name of “MegaJOULE” (which may or may not be retained as a product identifier).

Beam profiles were obtained for the subject VaporMAX LDD and predicate VaporMAX prior to the accumulation of multiple incremental changes and with each step that has potential for altering the output of the laser fiber and studies were performed to access the reproducibility of key performance variables (as measured by beam profiles and divergence as well as in simulated surgery with tissue phantoms). The subject fibers’ construction integrity was then tested with tensile strength measurements of cap retention on the fiber, orientation tube retention within the control knob, and fiber retention within the laser connector, all fibers surpassed design specifications. The subject devices are determined to be as safe and as effective as the lower power capable predicate devices even when used at the maximum power output of modern surgical lasers.

* To test caps retention and erosion under extreme conditions, abusive tests were performed, e.g., cutting a tissue phantom in half, e.g., a London broil steak, at 100 watts and 150 (watts with less than 10,000 joules).

Manufacturing, Packaging and Sterilization Facility:

Subject devices are designed, manufactured, packaging and sterilized within the InnovaQuartz manufacturing facility located in Phoenix, Arizona. All manufacturing equipment has been validated as appropriate for the intended functions and the product sterilization is compliant with ISO 11135:2014 standards. Shelf life is three years when stored as directed.

Conclusion:

A direct comparison of key characteristics demonstrates that subject devices are substantially equivalent to the predicate device in terms of materials of construction, intended uses, technological considerations, & performance. The subject devices are as safe, as effective, and perform as well as the predicate devices.