December 16, 2021

Ellex Medical Pty Ltd.
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
44 Oak Street
Stoneham, MA 02180

Re: K212630
Trade/Device Name: Ellex YAG/SLT Laser (Tango, Solo, Ultra Q, Tango Reflex, Ultra Q Reflex)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: November 9, 2021
Received: November 10, 2021

Dear Maureen O'Connell:

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,

for Tieuvi Nguyen, Ph.D.
Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K212630

Device Name
Ellex YAG/SLT Laser (Tango, Solo, Ultra Q, Tango Reflex, Ultra Q Reflex)

Indications for Use *(Describe)*
In the YAG mode (Tango, Ultra Q, Ultra Q Reflex, Tango Reflex):
-Iridotomy and iridectomy.
-Posterior capsulotomy.
-Posterior membranectomy.

In the SLT mode (Tango, Solo, Tango Reflex):
-Selective Laser Trabeculoplasty (SLT)

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
21 CFR 807.92
K212630

I. Submitter

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Date of preparation: 12/15/2021

II. Submission Correspondent

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44 Oak Street
Stoneham, MA 02180
Phone: (978) 207-1245

III. Proposed Device

Trade Name: Ellex YAG/SLT Laser (Tango, Solo, Ultra Q, Tango Reflex, Ultra Q Reflex)
Manufacturer: Ellex Medical Pty Ltd
Common or Usual Name: Ophthalmic laser

Classification:

Class	Product Code	Device Classification Name	Regulation Number	Regulation Name	Reviewing Branch
II	HQF	Laser, Ophthalmic	21CFR 886.4390	Ophthalmic Laser	Ophthalmic

IV. Legally marketed Device /Predicate Device

Device name: Lumenis Selecta Duet

Premarket Notification: K021550

Manufacturer: Ellex Medical Pty Ltd

V. Device Technological characteristics

These devices are slit lamp based surgical laser instruments designed for use by ophthalmologists in clinics or an outpatient facility in a hospital or surgery. These systems are used to perform both Photodisruption procedures such as posterior capsulotomies, iridotomies, posterior membranectomies in the photodisruptor (YAG mode) and Selective Laser Trabeculoplasty (SLT mode) for the treatment of chronic open angle glaucoma.

There are 5 models in this device family and their differentiating characteristics are mentioned below :

Models	Treatment beams/mode	Aiming beams	Illumination mirror	Display
Tango Reflex	YAG (1064nm)	Green, 515nm	Reflex Coaxial	Tablet
	SLT (532 nm)	Red ,635nm		

Tango	YAG (1064nm)	Red ,635nm	Fixed	Remote control unit
	SLT (532 nm)	Red ,635nm		
Ultra Q Reflex	YAG (1064nm)	Red ,635nm or Green ,515nm	Reflex Coaxial	Remote control unit
Ultra Q	YAG (1064nm)	Red ,635nm	Fixed	Remote control unit
Solo	SLT (532 nm)	Red ,635nm	Fixed	Remote control unit

All these devices consist of the below main parts:

Delivery Head

The delivery head comprises an ophthalmic slit lamp microscope with an integrated treatment laser beam and a twin aiming laser beam system.

Microscope and Slit lamp Illumination

The microscope or biomicroscope comprises three main components, an objective lens, a magnification changer, and a binocular. The combination of these allows the physician to view into the patient's eye. The magnification changer allows for magnification adjustment between fixed magnification settings. The binocular can be adjusted to accommodate the physician's vision and pupillary distance. The objective lens is fixed and determines the microscope focal distance. Microscope illumination light is provided from the slit lamp through a halogen or LED lamp. An illumination mirror is located above the slit lamp, near the microscope's visual axis. The mirror reflects the illumination from the source towards the focal plane and patient's eye. While the illumination mirror is fixed for Tango/Solo/Ultra Q as in the predicate device Selecta Duet; the mirror for Tango Reflex

and Ultra Q Reflex is a flipping mirror.

This illumination mirror on the Tango Reflex and Ultra Q Reflex is located at a height directly on the viewing axis of the microscope and provides illumination which is co-axial to the viewing path. The mirror is narrow so the physician can see past it on either side when it is located (on its central axis) to be on-axis with the objective lens. In YAG mode, the aiming beams pass above and below the mirror. During firing, the mirror is rapidly moved out of the way so the YAG treatment beam can pass. Its movement is rapid enough not to cause a noticeable interruption in illumination.

Console and Table Top: It consists of the Patient handles, the Key switch, Emergency stop switch and the Laser on-off push button. Main components such as a Power Supply Unit (DC PSU), a YAG PSU, and voltage capacitors for initiating the laser beam generation are built inside the console.

Joystick fire button: It is used to trigger the emission of a laser pulse by pressing a button.

Total solution table: It is used to support the console and the tabletop. It also has the function to adjust the height of the tabletop.

Display unit: The operation of various functions is displayed on the tablet /Remote control unit , and the display unit controls and operates them.

VI. Principle of Operation

The Ellex YAG/SLT family of products are surgical laser instruments designed for use by ophthalmologists for performing both Photodisruption procedures such as posterior capsulotomies, iridotomies, posterior membranectomies and Selective Laser Trabeculoplasty (SLT) for the treatment of chronic open angle glaucoma. The instrument is capable of producing short, individual pulses of focused light with wavelengths of either 1064nm (YAG) or 532nm (SLT), depending on the mode of operation selected. The pulses can be accurately positioned on a structure within the patient's eye with the aid of a slit-lamp microscope and a 635nm (red) / 515 nm (green) aiming beam system.

When the YAG mode is selected, the treatment wavelength is 1064nm. A twin-aiming beam is used to position the treatment beam into the area where the tissue disruption process is to occur. The energy contained within a single short pulse is concentrated by focusing to a very small spot size (approximately 8 microns) so that plasma formation occurs at the focal point. This creates an acoustic shock wave that disrupts nearby tissue.

When the SLT mode is selected, the treatment wavelength is 532nm. A coaxial aiming beam is used to position the treatment beam onto the trabecular meshwork via an SLT gonioscope contact lens. The SLT treatment laser provides a low energy, short pulse of laser light that selectively targets and damages only the pigmented cells in the trabecular meshwork of the eye; the resulting cellular activity restores the aqueous outflow through the trabecular meshwork and lowers the intraocular pressure.

VII.Indications for Use

In the YAG mode (Tango, Ultra Q, Ultra Q Reflex, Tango Reflex):
-Iridotomy and iridectomy.
-Posterior capsulotomy.
-Posterior membranectomy

In the SLT mode (Tango, Solo, Tango Reflex):
-Selective Laser Trabeculoplasty (SLT)

VIII. Summary of Non-Clinical Tests

The device has been evaluated for acoustic output, biocompatibility, as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform to the applicable medical device safety standards as below:

- **Safety and Product Specific testing:**

  Electrical safety, EMC and laser safety tests were conducted on Ellex YAG/SLT, according to applicable federal and international safety and performance standards:

ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012 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 compatibility-Requirements and tests

IEC 60601-l-6:2010+Al:2013 Medical electrical equipment-Part 1-6: General requirements for safety-Collateral Standard Usability

IEC 60601-1-8: 2006 (2nd Ed) + A1:2012 Medical electrical equipment – Part 1-8: Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-2-22: 2007 (Third Edition) + Al:2012 Medical Electrical Equipment Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

IEC 60825-1 2nd Edition Part I: Safety of laser products-Part I: Equipment classification and requirements

- **Biocompatibility Testing**

There are no direct patient components in Ellex YAG/SLT devices except for the chin rest and the head rest components of the slit lamp. These can be classified as “surface contacting devices in contact with intact skin” and as devices whose cumulative single, multiple or repeated use or contact is up to 24 hours. The Ellex slit lamps have been previously cleared by their manufacturers. The Takagi slit lamp has been FDA cleared under K063352 and the CSO slit lamp under K992836.

- **Software Verification and Validation Testing**

According to the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)", the level of concern of Ellex YAG/SLT devices and its software is determined to be Major. The Software of these devices controls the delivery of laser energy. A failure of operation or latent flaw of these devices' software could directly result in serious injury to the patient or operator.

The software verification and validation results confirm the fulfillment of software requirement specifications.

- **Risk Analysis Method Used**

Ellex Medical Pty Ltd applied ISO-14971 to the design and development of the Ellex YAG/SLT devices. The conclusion from the risk analysis was the device was safe for its intended use and does not pose any unacceptable risks.

IX. Summary of Clinical Tests

Since the Ellex YAG/SLT devices use the same technology and principles as the predicate device, clinical data is not required.

X. Substantial Equivalence Discussion

The predicate device is the Ellex Selecta Duet cleared in K021550.

The Indications for Use for Ellex YAG/SLT devices are exactly the same as the predicate Selecta Duet.

Technological characteristics of the Ellex YAG/SLT devices are similar with respect to the basic design and function of the predicate device. Both the subject and predicate device are based on the same photo disruption and selective photothermolysis principles. The major technological aspects are in common between the predicate device and the Ellex YAG/SLT devices :

- Same wavelength, laser class, pulse duration, pulse setting and spot size for the treatment beam.

- Same beam configuration , spot sizes and safety class for the aiming beams.
- Same slit lamp microscope, magnification settings, slit lamp working length, slit lamp controls, chinrest and controls, slit lamp joystick and laser firing mechanism (fire switch).
- The systems have been designed in compliance with approved electrical and physical safety standards.

Technological advancements with respect to Reflex mirror illumination (Ultra Q Reflex and Tango Reflex), inclusion of the Green aiming beam with established laser safety for better contrast and visualization of the ocular structures in YAG mode, other differences related to user preferences or advancements based on marketed devices do not impact the safety or effectiveness of the devices in terms of the required treatment regimen as these are prescription devices under the control of trained ophthalmologist.

These modifications have been verified through the Non Clinical testing mentioned above.

XI. Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the subject Ellex YAG/SLT models met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate device.