July 15, 2022

Lumenis Be, Inc.
Shlomit Segman
Sr. Director, Regulatory Affairs
1870 South Milestone Drive
Salt Lake City, UT 84104

Re: K220877
Trade/Device Name: Selecta Duet LED, Digital Duet, Selecta LED Trio, Digital Trio Laser Systems
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: March 14, 2022
Received: March 25, 2022

Dear Shlomit Segman:

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,

Anjana Jain, PhD
Assistant 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)*
K220877

Device Name
Selecta Duet LED, Digital Duet, Selecta LED Trio, and Digital Trio Laser Systems

Indications for Use *(Describe)*

- Selecta Duet LED or Digital Duet: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), iridotomy/ iridectomy, and selective laser trabeculoplasty.

- Selecta LED Trio or Digital Trio: Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), iridotomy/ iridectomy, selective laser trabeculoplasty, and retinal photocoagulation.

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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K220877

510(k) SUMMARY

PREPARATION DATE:	July 14, 2022
APPLICANT:	Lumenis Be, Inc. 1870 South Milestone Drive Salt Lake City, Utah 84104
CONTACT PERSON:	Shlomit Segman, PhD Sr. Director, Regulatory Affairs Lumenis Be Ltd. Tel: +972-4-9599230 or +972-52-3667233
DEVICE TRADE NAME:	Selecta Duet LED Laser System Digital Duet Laser System Selecta LED Trio Laser System Digital Trio Laser System
CLASSIFICATION NAME:	Powered Laser Surgical Instrument
DEVICE CLASSIFICATION:	Class II (21CFR§886.4390)
PRODUCT CODE:	HQF
PREDICATE DEVICE:	Selecta Duet and Trio Laser Systems Applicant: Lumenis, Inc. 510(k) Number: K081704 Classification Name: Powered Laser Surgical Instrument Device Classification: Class II (21CFR§878.4810) Product Code: GEX, HQF The Selecta Duet and Trio Laser Systems have not been subject to a design related recall.

DEVICE DESCRIPTION:

The Selecta Duet LED and Digital Duet subject devices are each a fully integrated, high-performance diagnostic slit lamp and therapeutic laser delivery system. The diagnostic slit lamp is for examining the anterior segment of the eye, from the corneal epithelium to the posterior capsule. The integrated Nd:YAG Q-Switch laser module provides short pulses at the wavelength corresponding with the selected operating mode. Two modes are available:

- PD (YAG) mode: 1064 nm for photodisruption (PD) of ocular tissues in procedures such as posterior capsulotomy, iridotomy, and iridectomy, and
- SLT mode: 532 nm for Selective Laser Trabeculoplasty (SLT).

The Selecta LED Trio and Digital Trio subject devices are each created by connecting the Selecta LED Duet and Digital Duet, respectively, to a compatible, FDA-cleared, Lumenis continuous 532 nm wavelength photocoagulator laser, via the LaserLink S. When the user connects the Duet to the LaserLink S, the Duet-part acts only as a Slit Lamp since the integrated Duet-laser is disabled and the laser in the external photocoagulator takes over. This combination adds the ability to perform retinal photocoagulation, as well as other indications cleared for the continuous 532 nm wavelength photocoagulator laser. The user disconnects the Duet from the LaserLink S for the system to perform as a Duet.

INTENDED USE/INDICATIONS FOR USE:

- **Selecta Duet LED or Digital Duet:** Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), iridotomy/ iridectomy, and selective laser trabeculoplasty.

- **Selecta LED Trio or Digital Trio:** Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), iridotomy/ iridectomy, selective laser trabeculoplasty, and retinal photocoagulation.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The subject laser systems are substantially equivalent to their respective predicate, predecessor K081704 laser systems. This is a catch-up 510(k) submission intended to update the Selecta Family of Laser Systems record at FDA with the changes that have been implemented in the subject devices. As such, the intended use/indications remain substantial equivalent to that for the cleared devices. Further, the implemented changes were primarily to be responsive to user feedback, upgrade to the latest user interface, or reflect a need to change a supplier or manufacturing contractor. The key changes are captured in the comparison table below.

Table: Comparison of Technological Characteristics

	Cleared Devices **Selecta Duet and Trio Laser Systems (K081704)**	**Subject Devices:** **Selecta Duet LED, Digital Duet, LED Trio, and Digital Trio Laser Systems**
	GENERAL	
Manufacturer	Lumenis, Inc.	Lumenis Be, Inc.
Regulation Number	21CFR§878.4810	Same
Regulation Name	Powered Laser Surgical Instrument	Same
Procodes	GEX and HQF	Same
Indications for Use	• **Selecta Duet:** Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy and selective laser trabeculoplasty. • **Selecta Trio:** Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), and discission of pupillary membranes (pupillary membranectomy) in aphakic and pseudophakic patients, and iridotomy/iridectomy, retinal photocoagulation and selective laser trabeculoplasty.	• **Selecta Duet LED or Digital Duet:** Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), iridotomy/ iridectomy, and selective laser trabeculoplasty. • **Selecta LED Trio or Digital Trio:** Photodisruption of ocular tissue using light energy emitted by a Nd:YAG laser, including discission of the posterior capsule of the eye (posterior capsulotomy), iridotomy/ iridectomy, retinal photocoagulation, and selective laser trabeculoplasty.
	LASER SPECIFICATIONS	
Type	Frequency-doubled/Q-switched Nd:YAG	Identical

	Cleared Devices **Selecta Duet and Trio Laser Systems (K081704)**	**Subject Devices:** **Selecta Duet LED, Digital Duet, LED Trio, and Digital Trio Laser Systems**
Principal output – wavelength	532 and 1064 nm	Identical
Operating mode	Frequency doubled/Fundamental, pulsed	Identical
Pulse duration	3 nanoseconds	Identical
Energy (mJ)	For 532 nm laser: 2 maximum For 1064 nm laser: 30 maximum	Identical
Laser beam spot size	For 532 nm laser: 400 µm at visual focal plane For 1064 nm laser: <8 µm full width half maximum	For 532 nm laser: 400 µm at visual focal plane For 1064 nm laser: <11 µm at visual focal plane, 8 µm full width half maximum calculated
CDRH Rad. Health classification	Class IIIb Lasers	Identical
IEC 60825 classification	Class 3B	Identical
Laser Actuation	Button or footswitch	Joystick button or Footswitch
AIMING BEAM SPECIFICATIONS		
Type	CW Diode laser	Identical
Principal output	635 nm wavelength	Identical
CDRH Rad. Health classification	Class II	Identical
IEC 60825 classification	Class 2	Identical
SLIT LAMP		
Field of view	11.3 mm diameter at 16X magnification	Identical
Working distance	70 mm	Identical

	Cleared Devices **Selecta Duet and Trio Laser Systems (K081704)**	**Subject Devices:** **Selecta Duet LED, Digital Duet, LED Trio, and Digital Trio Laser Systems**
Slit rotation (°)	-90 (horizontal) to + 90 (horizontal)	Identical
Bulb	Halogen, 30 W	Light Emitting Diodes, 5W
COMPATIBLE 532 nm PHOTOCOAGULATOR LASER		
	• Novus Spectra Laser System	• Smart532 (K151109)

The differences between the subject devices and their respective, predecessor, predicated devices do not raise different questions of safety and effectiveness and have been confirmed through testing.

PERFORMANCE TESTING:

Performance testing demonstrates that the subject devices are as safe and as effective as their respective, predicate, predecessor devices. These tests included:

- Evaluating the implemented changes using the same recognized standards that were used for the cleared devices:

Standard Number	**Standard Name**
ANSI/AAMI ES60601-1:2005/ A2:2010	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2 Edition 4.0:2014	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 Ed. 3.1 b: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
ISO 15004-2	Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection
ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices

- Software/Bench Testing

  Lumenis developed and verified the software in accordance with a major level of concern described in the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and also per the IEC 62304:2006 and A1:2015 Medical Device Software - Software Life Cycle Processes standard.

  The software/bench tests conducted on the modifications confirmed that they met their requirements.

CONCLUSIONS:

The provided performance testing supports a substantial equivalence determination. The subject devices are substantially equivalent to their respective, predicate, predecessor devices.