June 11, 2020

E-swin
Emeric OBIN
Regulatory Affairs Manager
Rue des Cotes D'orval, ZA de la prevote
Houdan, Yvelines 78550
France

Re: K200616
Trade/Device Name: E>EyeC
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: ONF
Dated: April 13, 2020
Received: April 13, 2020

Dear Emeric OBIN:

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 and Part 809); 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,

Colin Kejing Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200616

Device Name
E>Eye C

Indications for Use *(Describe)*

The E>Eye is a prescription device intended for the treatment of rosacea

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) SUMMARY

1) Applicant Name:

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2) Contact Person:

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3) Date Prepared:

June 11, 2020

4) Trade Name:

E>EYE C

5) Regulatory Information

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code: ONF
Class: Class II
Regulation Number: 21 CFR 878.4810

Panel: General & Plastic Surgery

Predicate Devices: Lumenis M22 System (K170060) , DEKA LUXEA LAZUR Pulsed Light Handpiece (K192539)

Indications for Use: The complete phrasing of the indications for use statement is provided in the formal Indications for Use Statement (FDA Form 3881).

6) Intended use:

The E>Eye is a prescription device intended for the treatment of rosacea.

7) Device Description:

The E>Eye C is an intense pulsed light system composed of a base housing the electric and electronics sub-assemblies, and a handheld piece “applicator” connected to the base by a cord. The applicator contains the source of optical radiation.

8) Technological Characteristics and Substantial Equivalence:

The intended use and indications for use of the E>EYE C are the same as the selected predicate devices. In addition, the same technological characteristics and principles of operation apply for the E>EYE C and the predicate device.

	Predicate Device	Predicate Device	Device
Device Name	Lumenis M22 System IPL Handpiece (K170060)	DEKA LUXEA LAZUR Pulsed Light handpiece (K192539)	E>EYE C
Energy Medium	Flashlamp	Flashlamp	Flashlamp
Wavelength Range	400-1200nm	420-950nm	580-1200nm, cutoff before 580nm
Pulse Duration	40-100ms – multiple pulse	30, 40, 50 ms	170ms – multiple pulse
Energy Density	10-56J/cm²	3-20J/cm²	8-13j/cm²
Spot size	6cm²	6.2cm²	7.5cm²
Intended Use	Benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations	- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.	Treatment of rosacea

Minor differences can be found in spot size, wavelength and energy density. Those differences do not raise additional safety or effectiveness questions.

The E>EYE C has the same indications for use, same technology, comparable pulse duration as its predicates.

9) PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

NON-CLINICAL

Electrical safety and electromagnetic compatibility

(EMC) Electrical safety and EMC testing were conducted on the E>EYE C, composed of its base and its applicator/handpiece. The system complies with the IEC 60601-1, IEC 60601-2-57 standards for safety and the IEC 60601-1-2 standard for EMC.

Usability

Usability testing has been conducted, and the E>EYE C complies with IEC 60601-1-6.

Photobiological safety

Safety testing has been conducted, and the E>EYE C complies with IEC 62471.

Software Verification and Validation

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 software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could not directly result in serious injury or death to the patient or operator.

Clinical Data

None.

10) Conclusions:

The E>EYE C was found to perform as well as its predicate, to be as safe and effective for its intended use as its predicate, and is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issues.