August 20, 2021

Oculight Ltd.
% Robert Packard
President
Medical Device Academy, Inc.
345 Lincoln Hill Road
Shrewsbury, VT 05738

Re: K202670
Trade/Device Name: Nam illumination probe with chopper
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: MPA
Dated: July 10, 2021
Received: July 12, 2021

Dear Robert Packard:

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,

J Angelo Green -S

for LCDR Charles Chiang
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)*
K202670

Device Name
Nam illumination probe with chopper

Indications for Use *(Describe)*
The Nam illumination probe with chopper is used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization and manipulation during cataract surgery.

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 – K202670

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Oculight Co., Ltd.
Seongnamdaelo 1342, B111
Seongnam-si, Gyeonggi-do, 13120, Republic of Korea
Tel: +82-031-8039-6177
Fax: N/A

Contact Person: Robert Packard
Date Prepared: August 19, 2021

II. DEVICE

Name of Device: Nam illumination probe with chopper
Model 1: 0.5mm, general Angle and 0.5mm, general Angle
Model 2: 0.5mm Twisted and 0.64mm Twisted
Model 3: 0.55mm Bend and 0.64mm, Bent

Classification Name: Endoilluminator
Regulation: 21 CFR §876.1500
Regulatory Class: Class II
Product Classification Code: MPA

III. PREDICATE DEVICE

Predicate Manufacturer: Syntec, Inc.
Predicate Trade Name: Syntec, Inc. True Light Endoilluminator with Pick
Predicate 510(k): K973290

There were two 510(k)-exempt reference devices used in this submission to support the "chopper" component of the device. Both reference devices are similarly designed cataract surgical instruments that are registered with the FDA:

- Katena Products, Inc. (FDA Establishment registration: 1934420)
- Aesculap (FDA Establishment registration: 2916714)

An additional reference device (i.e. iVision Light Source) was used in this submission. The light source is a 510(k)-exempt device that was used for benchtop performance testing. This light source is registered with the FDA by Oculight Co., Ltd. (the submitter).

IV. DEVICE DESCRIPTION

This product transmits light through the optical fiber to the inside of the eye to illuminate the intraoperative field of the eyeball. It consists of tube, handle, optical fiber, fiber cloth, and connector.

V. INDICATIONS FOR USE

The Nam illumination probe with chopper is used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization and manipulation during cataract surgery.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

Feature	Subject Device (Nam illumination probe with chopper)	Predicate Device (K973290)	Basis for determination of Substantial Equivalence
Indications for Use	The Nam illumination probe with chopper is used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization and manipulation during cataract surgery.	The Syntec, Inc. Disposable Endoilluminator with Pick is used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization and to manipulate tissue, during vitreo-retinal surgery.	Subject device's indications are limited to cataract surgery, but this limitation eliminates risks of vitreo-retinal surgery.
Materials	Stainless steel tubing	Stainless steel tubing	Same
Design	Fiberoptic delivery of light from lamp accessory; Chopper is integrated into tip of tubing	Fiberoptic delivery of light from lamp accessory; Pick is integrated into tip of tubing	Both devices deliver light in the same manner, but instruments of slightly different are integrated into the tip of the device.
Components	tube, handle, optical fiber, fiber cloth, and connector	handpiece tube, optical fiber, sheath, and connector	The subject device and the predicate both enclose the optical fibers in a stainless tube, but the predicate device is held by a handle and the predicate has a "handpiece tube". The predicate has a sheath around the optical fiber, while the subject device uses a fiber cloth for the same purpose. Both devices have a connector for the light source.
Energy Source	N/A – not powered	N/A – not powered	Same
Sterilization Method	EO Sterilization	EO Sterilization	Same

VII. PERFORMANCE DATA

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

Sterilization & Shelf-life Testing

EO sterilization validation in accordance with ISO 11135
Shelf-life testing in accordance with ASTM F1980-16
Sterility testing in accordance with USP<71>
EO residual testing in accordance with ISO 10993-7
Endotoxin testing in accordance with USP<85>

Biocompatibility Testing

Cytotoxicity testing in accordance with ISO 10993-5
Skin Irritation testing in accordance with ISO 10993-10
Sensitization testing in accordance with ISO 10993-10
Acute systemic toxicity in accordance with ISO 10993-11
Endotoxin testing in accordance with USP<85>
Material Mediated Pyrogenicity in accordance with USP<151>

Electrical safety and electromagnetic compatibility (EMC)

Not Applicable – not a powered device

Software Verification and Validation Testing

Not Applicable – device does not include software or firmware

Mechanical and acoustic Testing

Performance testing in accordance with ISO 15004-1 & ISO 15752
Shipping validation in accordance with ASTM D4169-16

Benchtop Performance Testing

Benchtop performance testing was performed in accordance with ISO 15752:2010 and ISO 15004-2:2007.

Animal Study

Animal performance testing was not required to demonstrate substantial equivalence of the device.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate substantial equivalence of the device.

VIII. CONCLUSIONS

The results of the testing performed demonstrate that the subject device is substantially equivalent when compared with the predicate device.