June 28, 2024

Bio Optics Co., Ltd.
Gayun Kim
Manager of KMC Inc.
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
Korea, South

Re: K241229
Trade/Device Name: Hello,eyes® BIO Plug
Regulatory Class: Unclassified
Product Code: LZU
Dated: May 2, 2024
Received: May 2, 2024

Dear Gayun Kim:

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,

J Angelo Green -S

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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.

Submission Number *(if known)*

K241229

Device Name

Hello,eyes® BIO Plug

Indications for Use *(Describe)*

Hello,eyes® BIO Plug is intended to temporarily block tear drainage by the occlusion of the canaliculus in order to

- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Temporarily enhance the efficacy of topical medications or ocular lubricants,
- Temporarily treat contact lens intolerance secondary to dry eye,
- Temporarily treat dry eye after ocular surgery, and,
- Determine the potential effectiveness of permanent occlusion.

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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Date Prepared: June 11th, 2024

1. 510(k) Submitter

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2. Official Correspondent

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3. Device Information

- Trade Name/Device Name: Hello, eyes® BIO Plug
- Common name: Intracanalicular Plug
- Classification Regulation: Unclassified
- Device Class: Unclassified
- Panel: Ophthalmic
- Product Code: LZU

4. Predicate Device

The subject device is substantially equivalent to the following predicate devices
: K162361, SOFT PLUG® Extended Duration 180 Canalicular Plug by OASIS Medical, Inc.

5. Device Description

Intracanalicular Plug named Hello,eyes® BIO Plug consists of lacrimal punctum plug and its holder. The plug is made of polydioxanone per 21 CFR 878.4840. The pigment for the violet dye is D&C Violet No.2 per 21 CFR 74.3602. It is 2.0mm long and available in three diameters: 0.3, 0.4, and 0.5mm which are based on USP synthetic absorbable suture diameters. Hello,eyes® BIO Plug, the intracanalicular plug is a product sterile by ethylene oxide (EO) gas in accordance with ISO 11135:2014. It is designed to be inserted through the punctal opening and reside in the canaliculus until it is absorbed over time in tissue.

6. Indication for use

Hello,eyes® BIO Plug is intended to temporarily block tear drainage by the occlusion of the canaliculus in order to
- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Temporarily enhance the efficacy of topical medications or ocular lubricants,
- Temporarily treat contact lens intolerance secondary to dry eye,
- Temporarily treat dry eye after ocular surgery, and,
- Determine the potential effectiveness of permanent occlusion.

7. Substantial Equivalence Discussion

7.1 Comparison Table

	Subject Device	Predicate Device	Comparison
Manufacturer	Bio Optics Co., Ltd.	OASIS Medical, Inc.	-
Device Name	Hello, eyes® BIO Plug	SOFT PLUG® Extended Duration 180 Canalicular Plug	-
510(k) No.	K241229	K162361	-
Product Code	LZU	LZU	Same
Indication for Use	Hello, eyes® BIO Plug is intended to temporarily block tear drainage by the occlusion of the canaliculus in order to - Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases, - Temporarily enhance the efficacy of topical medications or ocular lubricants, - Temporarily treat contact lens intolerance secondary to dry eye, - Temporarily treat dry eye after ocular surgery, and, - Determine the potential effectiveness of permanent occlusion.	The SOFT PLUG® Extended Duration 180 Canalicular Plugs are intended to temporarily block tear drainage by the occlusion of the canaliculus in order to - Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases, - Temporarily enhance the efficacy of topical medications or ocular lubricants, - Temporarily treat contact lens intolerance secondary to dry eye, - Temporarily treat dry eye after ocular surgery, and, - Determine the potential effectiveness of permanent occlusion	Same
Intracanalicular Punctum Plug	Yes	Yes	Same
Intended Duration	Approximately 90 Days	Approximately 180 Days	Different
Material	Polydioxanone (PDO)	Polydioxanone (PDO)	Same
Color Additive	D&C Violet No. 2	D&C Violet No. 2	Same
Shape	Cylindrical	Cylindrical	Same
Diameter Availability	0.3-0.5(mm) which are based on USP synthetic absorbable suture diameters	0.2-0.5 (mm) which are based on USP synthetic absorbable suture diameters	Similar
Length	2.0 (mm)	2.0 (mm)	Same
Sterilization	EO Sterilization	EO Sterilization	Same
Single Use	Yes	Yes	Same

7.2 Technical Characteristics

1) Same/Similar Points between subject device and predicate device

Item	Description
Product Code	The product code(LZU) is same between subject device and predicate device.
Indication for Use	The indication for use is same between subject device and predicate device.
Intracanalicular Punctum Plug	The subject device is Intracanalicular Punctum Plug. It is same with the predicate device.
Material	The material of subject device is Polydioxanone (PDO). It is same with the predicate device.
Color Additive	The color additive of subject device is D&C Violet No. 2. It is same with the predicate device.
Shape	The shape of subject device is Cylindrical. It is same with the predicate device.

Item	Description
Diameter Availability	The diameter availability of the subject device is “0.3-0.5(mm) which are based on USP synthetic absorbable suture diameters”. The diameter availability of the predicate device is “0.2-0.5 (mm) which are based on USP synthetic absorbable suture diameters”. It is similar with the predicate device.
Length	The length of subject device is 0.2mm. It is same with the predicate device.
Sterilization	The sterilization of subject device is E.O sterilization. It is same with the predicate device.
Single Use	The subject device is single use. It is same with the predicate device.

2) Different Points between subject device and predicate device

Item	Description
Intended Duration	The Intended duration of the subject device is “Approximately 90 Days”. The Intended duration of the predicate device is “Approximately 180 Days”. These differences in intended duration do not raise different questions of safety and effectiveness because intended duration of the subject device has a shorter contact time within the human body than the predicate device. The intended duration (approximately 90 days) was supported by an animal implantation study.

7.3 Comparison conclusion to predicate device

Subject device and Predicate device have the same Indication for use, material, color additive, shape, diameter, length, sterilization, and single use, and the only difference is Intended Duration. However, The intended duration (approximately 90 days) was supported by an animal implantation study. Any differences do not raise different questions of safety and effectiveness than the predicate. Therefore, there is no difference between the subject and predicate with respect to the indications or technology. Therefore, the subject device is substantially equivalent to the predicate device.

8. Summary of Non-Clinical Testing:

Below tests were performed on the subject device:

Non clinical tests were conducted to verify that the subject device(Hello,eyes® BIO Plug) met all design specifications as was Substantially Equivalent (SE) to the predicate device(K162361). The test results demonstrated that the proposed device complies with the following standards.

- Sterilization Validation Report on Hello,eyes® Bio Plug according to ISO 11135:2014
- Pre-sterilization Bioburden Determination, ISO 11737-1:2018
- Shelf Life Test report on Plug and Holder according to ISO11607-1:2019, ISO11607-2:2019
- Cytotoxicity testing according to ISO 10993-5:2009
- Sensitization testing according to ISO 10993-10:2010
- Intracutaneous testing according to ISO 10993-10:2010
- Acute Systemic Toxicity testing according to ISO 10993-11:2017
- Pyrogenicity (Material-mediated pyrogenicity) testing according to ISO 10993-11:2017
- Subchronic toxicity testing according to ISO 10993-11:2017
- Genotoxicity testing according to ISO 10993-3:2014
- Implantation testing according to ISO 10993-6:2016
- Carcinogenicity and chronic toxicity which were assured by used chemical characterization and toxicological risk assessment according to ISO 10993-1:2018 and ISO 10993-18:2020.
- LAL, Bacterial Endotoxin Testing on Hello,eyes® Bio Plug according to ANSI/AAMI ST72:2019.

▪ Chemical characterization and Toxicological Risk Assessment on Hello,eyes® Bio Plug according to ISO10993-18

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

Conclusion

The Hello,eyes® Bio Plug, subject device of this submission, constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, Hello,eyes® Bio Plug and its predicates are substantially equivalent.