July 3, 2024

The Standard Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
Irvine, California 92612

Re: K241591
Trade/Device Name: Blue Eye
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: PLL
Dated: June 3, 2024
Received: June 3, 2024

Dear Priscilla Chung:

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,

Sivakami Venkatachalam -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241591

Device Name

Blue Eye

Indications for Use *(Describe)*

The Blue Eye is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or endoscopic device.

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

Date: June 1, 2024

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR 807.92.

1. Submitter:

Name	The Standard Co., Ltd.
Address	120, Gunpocheomdansaneop 2-ro, Gunpo-si, Gyeonggido, 15880, Republic of Korea
Phone	+82 2 838-5533
Fax	+82 2 838-5523
Contact	Mr. Sang-wook, Yang / QMR
Date prepared	May 10, 2024

2. Device Information:

- Trade name: Blue Eye
- Common name: Submucosal injection agent
- Classification name: Endoscope and Accessories (21CFR 876.1500, Product code: PLL)

3. Predicate Device:

- Blue Eye (K220434) manufactured by The Standard Co., Ltd.

Blue Eye (TS-910) [subject device] is substantially equivalent in term of its in terms of its intended use to the claimed predicate device, the 5mL Blue Eye (TS-905) (K220434) with respect to device design, fundamental technology, physical characteristics, performance and intended use.
The device design and fundamental technology of the subject device are nearly identical to that of the predicate device. The formulation and composition of the primary packaging materials are identical. There are slight differences in the dimensions of the subject device and predicate device which do not impact safety or effectiveness. Both the subject and predicate devices are delivered sterile and are indicated for single-use only.

4. Device Description:

Blue Eye, submucosal injection agent, is a solution used for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or

endoscopic device in gastrointestinal endoscopic procedures. The main materials of the solution are sodium hyaluronate and saline, and it is provided in prefilled syringe. It is supplied sterile and disposable.

Blue Eye is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or endoscopic device.

5. Summary of the technical characteristics between the new device and the predicate:

	Subject Device	**Predicate Device**	**Differences**
Manufacturer	The Standard Co., Ltd.	The Standard Co., Ltd.	-
Device Name	Blue Eye (TS-910)	Blue Eye (TS-905)	-
510(k) numbear	-	K220434	-
Product Code	PLL	PLL	Same
Device Class	Class II	Class II	Same
Classification Name	Endoscope and accessories	Endoscope and accessories	Same
Device Common Name	Submucosal Injection Agent	Submucosal Injection Agent	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Indication for Use	The Blue Eye is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or endoscopic device.	The Blue Eye is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or endoscopic device.	Same
Prescription or Over-the-Counter (OTC) Use	Prescription Use	Prescription Use	Same
Anatomical Site	gastrointestinal mucosal lesions	gastrointestinal mucosal lesions	Same
Target Population	Regular Adults (exclusion for pregnant or lactating women or children under 18 years of age)	Regular Adults (exclusion for pregnant or lactating women or children under 18 years of age)	Same
Sterilization method	Steam sterilization	Steam sterilization	Same

	Subject Device	Predicate Device	Differences
Packaging	Provided in 10 mL single-use prefilled syringe packed inside a Tyvek paper and tray. Ten (5) of the sealed trays are packed into a paper box.  [Paper box]	Provided in 5 mL single-use prefilled syringe packed inside a Tyvek paper and tray. Ten (10) of the sealed trays are packed into a canister.  [Canister]	Different. The secondary packaging material and capacity are different.
Composition	Each steam sterilized syringe contains 10mL of lifting agent with the following ingredients: • Water • Hydroxyethyl Cellulose • Glycerin • Methylene Blue • Benzyl Alcohol • Sodium Phosphate • Potassium phosphate	Each steam sterilized syringe Contains 5mL of lifting agent with the following ingredients: • Water • Hydroxyethyl Cellulose • Glycerin • Methylene Blue • Benzyl Alcohol • Sodium Phosphate • Potassium phosphate	Same concentration; however, Capacity of lifting agent provided differs.

Blue Eye (TS-910) described in this 510(k) has the same intended use and the same technical characteristics as the unmodified device.

The subject device and the unmodified device are substantially equivalent, having the same indications for use and raw materials including chemical compositions.
The modifications are in volume and secondary packaging material to meet customer needs.

Based on the test results submitted in this 510K, we conclude that the subject device is substantially equivalent to the predicate device.

6. Summary of Performance data

The determination of substantial equivalence is based on an assessment of non-clinical performance data. To verify that the device design modifications meet the functional and performance requirements, the Blue Eye (TS-910) underwent the following performance testing.

The tests were performed on the subject device using the same method as the predicate device, and acceptance criteria.

- Syringe performance / ISO 11040-6, ISO 80369-7 and ISO 7886-1
- Transportation Validation and Shipping test / ASTM D 4169: 2022
- Steam Sterilization Validation in heat distribution test, heat penetration test, BI test, Bioburden test and sterility test / ISO 17655-1, ISO 11737-1 and ISO 11737-2
- Packaging Validation / ASTM F 88/ F88M-23 and ASTM F 1929-15
- Shelf-life test ASTM F 1980-21

7. Conclusions:

Based on the results of the non-clinical performance testing conducted on the subject device, it has been concluded that the proposed Blue Eye (TS-910) is as safe and effective and performs as well as the legally marketed predicate device(K220434). The same indications for use, intended use, technological characteristics, and performance characteristics for the proposed Blue Eye (TS-910) have been assessed to be substantially equivalent to the predicate device, and any differences do not raise different issues of safety and effectiveness when compared to the predicate device. Therefore, Blue Eye (TS-910) is substantially equivalent to the predicate device.