August 12, 2022

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

Re: K220434
Trade/Device Name: Blue Eye (TS-905)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: PLL
Dated: February 3, 2022
Received: February 15, 2022

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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220434

Device Name
Blue Eye (TS-905)

Indications for Use *(Describe)*
The Blue Eye (TS-905) 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.

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

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510(k) Summary

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

Date: Feb 03, 2022

1. Company and Correspondent making the submission:

	Company
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. Seongnam Kim/ president

2. Device:
   Trade name: Blue Eye (TS-905)
   Common name: Submucosal injection agent
   Classification name: Submucosal injection agent, 21CFR 876.1500
   Product code: PLL

3. Predicate Device:
   SIC 8000, K150852(Product Code: PLL, 21CFR 876.1500) by Cosmo Technologies Ltd.

4. Description:
   The Blue Eye (TS-905), 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 gastrointenstinal 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.

5. Indication for use:
   The Blue Eye (TS-905) 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.

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

	Subject Device	**Predicate Device**	**Same/Similarities/Differences**
Manufacturer	The Standard Co., Ltd.	Cosmo Technologies Ltd.	---

Device Name	Blue Eye (TS-905)	SIC8000	---
510(k) #	-	K150852	---
Product Code	PLL	PLL	Same
Device Class	Class II	Class II	Same
Device 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 (TS-905) 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 SIC 8000 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

The Blue Eye (TS-905) is substantially equivalent to the predicate device, SIC 8000 (K150852) in terms of indications for use and technological characteristics. There are differences in raw materials, packaging, and shelf life, however, we conducted various tests including sterilization validation, shelf-life validation, and non-clinical performance tests and the results support that the subject device is substantially equivalent to the predicate device.

7. Brief discussion of the nonclinical tests

The following comparison tests were performed on the subject device. The test results show that the subject device is substantially equivalent to the predicate device in effectiveness.

- Sterilization validation per ISO 17665-1
- Shelf life validation per ASTM F1980-16
- Biocompatibility tests per ISO 10993-3, 5, 6, 10, 11
- Performance test: Characterization (ISO 10993-18), packaging (ASTM F88/F88M, ASTM F1929), Shipping (ASTM D4169), Syringe Performance (ISO 7886-1, ISO 80369-7 ISO 80369-20), Osmolality, pH, Viscosity

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, The Standard Co., Ltd. concludes that the Blue Eye (TS-905) is substantially equivalent to predicate devices as described herein.