June 20, 2020

GI Supply, Inc.
Erika Parry
Manager, Quality & Regulatory
5069 Ritter Road, Suite 104
Mechanicsburg, PA 17055

Re: K191923
Trade/Device Name: EverLift Submucosal Lifting Agent
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: PLL
Dated: May 20, 2020
Received: May 22, 2020

Dear Erika Parry:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191923

Device Name
EverLift Submucosal Lifting Agent

Indications for Use *(Describe)*
EverLift Submucosal Lifting Agent is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers, or other gastrointestinal lesions prior to excision with a snare or other appropriate 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.

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
Food and Drug Administration
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

I. SUBMITTER [Per 807.92(a)(1)]

Sponsor / Manufacturer
GI Supply
5069 Ritter Road
Suite 104
Mechanicsburg, PA 17055 USA
Phone: (800)-451-5797

Contact Person
Erika Parry
Manager, Quality & Regulatory
Phone: (717)-562-7580
Email: e.parry@gi-supply.com

Date Prepared
July 19, 2019
Amended June 19, 2020

II. DEVICE [Per 807.92(a)(2)]

Device Trade/Proprietary Name:	**EverLift™ Submucosal Lifting Agent**
Device Common or Usual Name:	Submucosal Injection Agent
Device Classification Name:	Endoscope and Accessories
Device Regulatory Classification:	Class II
Device Classification Regulation:	21 CFR 876.1500
Product Code:	PLL
Submission Type:	510(k)
Classification Panel:	Gastroenterology/Urology

III. PREDICATE DEVICE [Per 807.92(a)(3)]

The EverLift™ Submucosal Lifting Agent (subject device) is substantially equivalent in terms of its indications for use / intended use for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early stage cancers, or other gastrointestinal lesions, prior to excision with a snare, forceps, or other appropriate endoscopic device, when compared to the predicate device, the Cosmo Technologies Ltd. SIC 8000 (Eleview Submucosal Injectable Composition) (K150852). Please refer to the table below for additional details.

Predicate Device	The EverLift™ Submucosal Lifting Agent (subject device) is substantially equivalent to the following predicate device, manufactured by Cosmo Technologies Ltd.: • SIC 8000 (Eleview Submucosal Injectable Composition (K150852) The EverLift™ Submucosal Lifting Agent (subject device) is substantially equivalent in terms of its indications for use / intended use for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early stage cancers, or other

	gastrointestinal lesions, prior to excision with a snare, forceps, or other appropriate endoscopic device, when compared to the predicate device, the Cosmo Technologies Ltd. SIC 8000 (Eleview Submucosal Injectable Composition) (K150852). Substantial Equivalency (SE) of the subject device has also been based on substantially equivalent usability, functionality, and performance characteristics as the predicate device.

IV. DEVICE DESCRIPTION [Per 807.92(a)(4)]

The GI Supply EverLift™ Submucosal Lifting Agent is a prefilled plastic syringe with attached plunger rod containing 5mL of lifting agent. The syringe has a luer lock connection capable of interfacing with a standard, commercially available, endoscopic injection needle.

The EverLift™ Submucosal Lifting Agent is an injectable liquid composition for use as a submucosal injection agent during endoscopic mucosal resection (EMR), endoscopic mucosal dissection (ESD) and polypectomy procedures in the gastrointestinal tract. The device is intended for use in endoscopic resection procedures in the upper and the lower gastrointestinal tract, including the esophagus, the stomach, the small intestine, the colon, the sigmoid colon, and the rectum, as a submucosal injectable agent during the removal of polyps, adenomas, early-stage cancers and other pathological lesions by EMR, ESD or polypectomy.

EverLift™ Submucosal Lifting Agent is injected into the submucosal layer by means of a standard, commercially available, endoscopic injection needle, which is inserted into the working channel of the endoscope. The composition, when injected, creates a cushion in situ by lifting the gastrointestinal mucosa from the submucosal layer, allowing the endoscopist to perform an easy and safe resection procedure (EMR, ESD or polypectomy).

IV. INTENDED USE / INDICATIONS FOR USE [Per 807.92(a)(5)]

Intended Use / Indications for Use
EverLift™ Submucosal Lifting Agent is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers, or other gastrointestinal lesions prior to excision with a snare or other appropriate endoscopic device.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [Per 807.92(a)(6)]

The EverLift™ Submucosal Lifting Agent [subject device] is substantially equivalent to the Cosmo Technologies Ltd. SIC 8000 (Eleview Submucosal Injectable Composition (K150852) [predicate device] based on the same indication for use as the predicate device, and the similar or identical functional and performance characteristics of the subject device when compared to the predicate device. The differences between the subject device and predicate device do not raise different issues of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence.

The detailed substantial equivalence comparison of the similarities and differences between the GI Supply EverLift™ Submucosal Lifting Agent (subject device) and the Cosmo Technologies Ltd. SIC 8000 (Eleview Submucosal Injectable Composition) (K150852) (predicate device) is provided in the table below.

Regulatory Information	EverLift™ Submucosal Lifting Agent (Subject Device)	SIC 8000 (Eleview Submucosal Injectable Composition (K150852) (Predicate Device)	Same/Similarities/Differences
Manufacturer	**GI Supply**	**Cosmo Technologies Ltd.**	--
Device Trade or Proprietary Name	**EverLift™ Submucosal Lifting Agent**	**SIC 8000 (Eleview Submucosal Injectable Composition)**	--
510(k) Number	K191923	K150852	--
Device Class	Class II	Class II	Same
Device Common Name	Submucosal Injection Agent	Submucosal Injection Agent	Same
Device Classification Name	Endoscope and Accessories	Endoscope and Accessories	Same
Product Code	PLL	PLL	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Indications for Use	EverLift™ Submucosal Lifting Agent is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers, or other gastrointestinal lesions prior to excision with a snare or other appropriate endoscopic device.	The SIC 8000 (Eleview Submucosal Injectable Composition) 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 other suitable endoscopic device.	Same
Intended Use	Same as Indications for Use	Same as Indications for Use	Same
Prescription or Over-the-Counter (OTC) Use	Prescription Use	Prescription Use	Same
Use Environment	Hospital / Clinic	Hospital / Clinic	Same
Sterile	Sterile	Sterile	Same
Single-Use	Single-Use Only	Single-Use Only	Same
Shelf Life	2-Year Shelf Life	3-Year Shelf Life	Different. The difference in shelf life duration does not raise different questions of safety and effectiveness. An accelerated aging study was performed on the subject device to confirm that the device meets all physical and functional requirements throughout a 2-Year Shelf Life.
Sterilization Method	EverLift™ Submucosal Lifting Agent is sterilized by moist-heat sterilization.	SIC 8000 (Eleview) is sterilized by filtration and aseptically filled.	Different. The difference in sterilization method does not raise different questions of safety and effectiveness.

Filling Method of Primary Container	Filled into a 5mL COC (cyclic olefin copolymer) syringe in an environmentally controlled ISO Class 7 cleanroom.	Aseptically filled into a 10mL polypropylene ampoule.	Different. The difference in filling methods of the primary containers does not raise different questions of safety and effectiveness.
Size and Material of the Primary Container	5mL COC (cyclic olefin copolymer) syringe	10mL polypropylene ampoule	Similar. The minor difference in size and material of the primary container does not raise different questions of safety and effectiveness. Biocompatibility Testing and Non-Clinical Performance Testing was conducted to demonstrate SE.
Design Features of the Primary Container	5mL COC pre-filled syringe (includes plunger) with Luer-lock connection that can easily be connected to a 23-gauge endoscopic injection needle with a needle length of 4 mm or less (not provided with the device).	10mL polypropylene ampoule with a female Luer-lock closure that can easily be connected to a suitable disposable plastic or glass syringe with male Luer-lock connection fitting, to extract the emulsion, and be injected through an endoscope via a normal, commercially available endoscopic injection needle (e.g.: a 2.3 mm x 230 cm endoscopic injection needle) having a needle diameter of 23 gauge (23G) or less (not provided with the device).	Similar. Design is similar, although composition of syringe/ampoule differs. Injection method is identical. The difference does not raise different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate SE.
Injection Method	Injected into the submucosal layer by means of a standard, commercially available, endoscopic injection needle, which is inserted into the working channel of the endoscope. The composition, when injected, creates a cushion in situ by lifting the gastrointestinal mucosa from the submucosal layer, allowing the endoscopist to perform an easy and safe resection procedure (EMR, ESD or polypectomy).	Injected into the submucosal layer by means of a standard, commercially available, endoscopic injection needle, which is inserted into the working channel of the endoscope. The emulsion, when injected, creates a cushion in situ by lifting the gastrointestinal mucosa from the submucosal layer, allowing the endoscopist to perform an easy and safe resection procedure (EMR, ESD or polypectomy).	Same
Storage Conditions	Store product at room temperature (15-30°C). Store in a dark place.	Store between 2°C (35.6°F) and 25°C (77°F). Excursions permitted up to 40°C (104°F).	Similar. The differences do not raise different questions of safety and effectiveness. Aging Studies were conducted to demonstrate SE.

How Provided to User	Provided in 5 mL single-use pre-filled syringes.	Provided in 10 mL single-use polypropylene ampoules pouched in an aluminum pouch under nitrogen, which is packed in a cardboard box.	Different. The difference in the use of a 5mL pre-filled syringe versus a 10mL ampoule do not raise different questions of safety and effectiveness. Biocompatibility Testing and Non-Clinical Performance Testing was conducted to demonstrate SE.
Use of Special Equipment	Does not require any special apparatus or equipment and is designed to be use with most common endoscopic resection devices.	Does not require any special apparatus or equipment and is designed to be used with the most common endoscopic resection devices.	Same
Composition	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	The emulsion consists of the following components: • Water for injection • Medium chain triglycerides • Poloxamer 188 • Polyoxyl-15Hydroxystearate • Sodium Chloride • Methylene Blue	Different. Both devices are formulated using water and methylene blue as the base formulation. Additives to increase surface tension, act as viscosifying agents, etc. differ slightly. The differences do not raise different questions of safety and effectiveness. Biocompatibility Testing and Non-Clinical Performance Testing was conducted to demonstrate SE.
Dosage and Administration	Remove the cap from the tube and remove the syringe. Examine the syringe to verify there is no damage. Then, using aseptic technique, attach the syringe to the Luer fitting on the endoscopic injection needle. A 23-gauge injection needle with a needle length of 4 mm or less is recommended for this procedure. Prime the needle with EverLift™ prior to injection. With the needle retracted, insert the needle's catheter through the biopsy working channel of the endoscope. When the needle is properly positioned, insert the tip at a 30°-45° angle to the surface into the submucosal space of the colon, ensuring the beveled tip of the needle is entirely beneath the mucosa. The maximum allowable dose is 50 mL per patient.	Eleview can be injected through an endoscope via a normal, commercially available endoscopic injection needle (e.g.: a 2.3 mm x 230 cm endoscopic injection needle) having a needle diameter of 23-gauge (23G) or less (not provided with the device). The administered dose of Eleview should be determined based on the dimensions of the lesion to be removed. Inject into the submucosa the amount of Eleview needed to form a submucosal cushion of optimal height and shape for the lesion to be removed. During the procedure do not exceed a total dose of 50 mL per patient, either in single or in multiple administrations.	Same

Rationale for Substantial Equivalence

The GI Supply EverLift™ Submucosal Lifting Agent [subject device] is substantially equivalent to the SIC 8000 (Eleview Submucosal Injectable Composition (K150852) [predicate device] in terms of the same indications for use / intended use and substantially equivalent usability, functionality, and performance characteristics as the predicate device. A detailed description of the similarities shared between the subject device and the predicate device, as well as, a description of the minor differences which do not raise new or different issues of safety and effectiveness, support a determination of substantial equivalency.

Similarities

The GI Supply EverLift™ Submucosal Lifting Agent [subject device] shares the following same or similar characteristics as the SIC 8000 (Eleview Submucosal Injectable Composition (K150852) [predicate device]:

- *Intended Use / Indications for Use* 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 other appropriate endoscopic device: Same
- *Sterile Device:* Same
- *Single-Use:* Same
- *Prescription Use:* Same
- *Use Environment:* Same

Additional features and functionality also shared among the subject device and the primary predicate and reference device include:

- *Injection Method:* Same
- *Dosage and Administration:* Same

Differences

There are minor differences that exist between the EverLift™ Submucosal Lifting Agent [subject device] when compared to the SIC 8000 (Eleview Submucosal Injectable) (K150852) [predicate device] which do not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE). The subject device has the following characteristics which are different from the predicate device:

- *Material / Ingredient Composition:* Similar. Both devices are formulated using water and methylene blue as the base formulation. Additives to increase surface tension, act as viscosifying agents, etc. differ slightly. The differences do not raise different questions of safety and effectiveness. Biocompatibility Testing and Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Size of Primary Container:* Different (5mL vs 10mL). The difference in size of the primary container does not raise different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Filling Method of Primary Container:* Different filling methods of the primary container are used. The different filling methods do not raise different questions of safety and effectiveness.

- *2-Year Shelf Life:* Different. The differences in shelf life do not raise different questions of safety and effectiveness. An Accelerated Aging Study was conducted on the subject device to confirm that the device meets all physical and functional requirements throughout a 2-year shelf life.
- *Sterilization Method:* Different. Different sterilization methods are used. The different sterilization methods do not raise different questions of safety and effectiveness.
- *How Provided to User:* Different. The difference in the use of a 5mL pre-filled syringe versus a 10mL ampoule do not raise different questions of safety and effectiveness.
- Biocompatibility Testing and Non-Clinical Performance Testing was conducted to demonstrate SE.

VI. SUMMARY OF PERFORMANCE DATA AND PERFORMANCE TEST CONCLUSIONS [Per 807.92(b)(1)(2)(3)]

The determination of substantial equivalence is based on an assessment of Non-Clinical Performance data. To verify that the device design meets its functional and performance requirements, the subject device underwent testing in accordance with the following.

The EverLift™ Submucosal Lifting Agent is developed under GI Supply's risk management process in accordance with ISO 14971:2007 - Medical Devices-Application of Risk Management to Medical Devices. The identified risks were adequately mitigated and verified by means of non-clinical performance testing.

Summary of Performance Testing

A series of functional performance tests, animal studies, biocompatibility tests, and sterility tests were conducted on the subject device. The following functional performance tests were performed: container closure integrity testing, syringe tip cap removal force testing, tube cap removal force testing, pH testing, product color evaluation, lift duration testing, and flow rate testing.

Comparative bench testing was conducted, which compared the proposed EverLift™ device to the predicate device Eleview® (K150852) for the following performance measures: viscosity, osmolality, and density.

Preclinical testing in a porcine model was conducted which compared the proposed EverLift™ device to the predicate device Eleview® (K150852).

Biocompatibility testing was conducted on the proposed EverLift™ device in accordance with ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process.

Bacterial endotoxin and pyrogen testing, in addition to chemical characterization testing, were also performed.

VII. CONCLUSIONS

The data generated from the results of the robust functional, performance, preclinical, and biocompatibility testing conducted on the EverLift™ Submucosal Lifting Agent [subject device] demonstrate that the device is as safe, as effective, and performs as well as the predicate device. Therefore, the data results may be relied on to support a determination of substantial equivalence.