September 30, 2020

Gi Supply, Inc.
Erika Parry
Manager, Quality and Regulatory
5069 Ritter Road Suite 104
Mechanicsburg, Pennsylvania 17055

Re: K202376
Trade/Device Name: EverLift Submucosal Lifting Agent
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: PLL
Dated: September 1, 2020
Received: September 2, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202376

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.

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"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 and Regulatory
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Date Prepared
August 19, 2020
Amended September 29, 2020

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

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

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

The EverLift™ Submucosal Lifting Agent (10mL) [subject device] is substantially equivalent in terms of its intended use to the claimed predicate device, the 5mL EverLift™ Submucosal Lifting Agent (5mL) (K191923) 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. The Sterilization Method and Shelf Life for the subject device are identical as that for the predicate device.

Predicate Device	The EverLift™ Submucosal Lifting Agent (10mL) [subject device] is substantially equivalent to the following predicate device manufactured by GI Supply: • **EverLift™ Submucosal Lifting Agent (5mL) (K191923)**

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

The GI Supply EverLift™ Submucosal Lifting Agent (10mL) is a prefilled plastic syringe with attached plunger rod containing 10mL of lifting agent. The syringe has a luer lock connection capable of interfacing with a standard, commercially available endoscopic injection needle.

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).

V. 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.

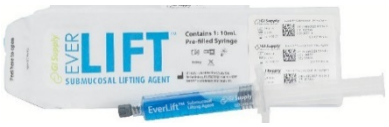
VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [Per 807.92(a)(6)]

The EverLift™ Submucosal Lifting Agent (10mL) [subject device] is substantially equivalent to the GI Supply EverLift™ Submucosal Lifting Agent (5mL) (K191923) [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.

The detailed substantial equivalence comparison of the similarities and differences between the GI Supply EverLift™ Submucosal Lifting Agent (10ml) [subject device] and the GI Supply EverLift™ Submucosal Lifting Agent (5mL) (K191923) [predicate device] is provided in the table below.

Regulatory Information	[Subject Device]	[Predicate Device]	Similarities / Differences
Manufacturer	**GI Supply**	**GI Supply**	Same
Device Trade or Proprietary Name	**EverLift™ Submucosal Lifting Agent (10mL)**	**EverLift™ Submucosal Lifting Agent (5mL)**	---

Regulatory Information	[Subject Device]	[Predicate Device]	Similarities / Differences
510(k) Number	K202376	K191923	---
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
Product Code	PLL	PLL	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Design Features and Capabilities of the Device			
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.	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.	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
Design Features			
Packaging	Each individual 10mL COC syringe is packed inside a thermoformed tray. The tray is sealed with a labeled lid stock with three (3) patient labels affixed to the lid stock. Ten (10) of the sealed trays are packed into a shelf box with a copy of the IFU placed between the trays and the shelf box wall. The shelf box is shipped in a regular die cut and scored 200-pound B-flute kraft shipper box sealed with a shipper box label.	Each individual 5mL COC syringe is packed along with three (3) patient labels inside a propionate tube with a friction fit press on closure. Ten (10) tubes are packed into a shelf box on top of a copy of the IFU. The shelf box is shipped in a regular die cut and scored 200-pound B-flute kraft shipper box sealed with a shipper box label.	Different. The differences in packaging do not raise different questions of safety or effectiveness. A Distribution Study was performed on the new packaging configuration.

Regulatory Information	[Subject Device]	[Predicate Device]	Similarities / Differences
Images of Device			---
Sterilization Method	Sterilized by moist-heat (steam) sterilization	Sterilized by moist-heat (steam) sterilization	Same
Shelf Life	2-Year Shelf Life	2-Year Shelf Life	Same
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, volume of lifting agent provided differs.

VII. 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 EverLift™ Submucosal Lifting Agent (10mL) underwent performance testing. Biocompatibility testing was performed only on the 5mL variant as it represented worst-case surface area to volume ratio.

The EverLift™ Submucosal Lifting Agent was developed under GI Supply's risk management process in accordance with ISO 14971:2012 - 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 non-clinical performance testing was conducted on the subject device. Please refer to the table below for a summary of all non-clinical performance testing conducted on the subject device in support of substantial equivalence.

Test Description	Conforming Standard(s)	Conclusion in Support of Substantial Equivalence
Syringe Tip Cap Removal Force Testing	None	Syringe tip cap removal force testing was performed on the subject device using the same method and acceptance criteria as the predicate device. Results of the testing confirmed that the syringe tip cap removal force is equivalent between the subject and predicate devices, thereby demonstrating substantial equivalence.

Test Description	Conforming Standard(s)	Conclusion in Support of Substantial Equivalence
Product Color Testing	None	Product color testing was performed on the subject device using the same method and acceptance criteria as the predicate device. Results of the testing confirmed that product color is identical between the two devices, thereby demonstrating substantial equivalence.
Injection Flow Rate Testing	None	Injection flow rate testing was performed on the subject device using the same method and acceptance criteria as the predicate device. Results of the testing confirmed that the injection flow rate is equivalent between the subject and predicate devices, thereby demonstrating substantial equivalence.
Graduation Marking Tolerance	ISO 7886-1:2017, Sterile hypodermic needles for single use – Part 1: Syringes for manual use	Graduation mark tolerance testing was performed on the subject device using the same method as the predicate device, and acceptance criteria as defined in ISO 7886-1. Results of the testing confirmed that the marking tolerance meets the acceptance criteria defined in ISO 7886-1, thereby demonstrating substantial equivalence.
Container Closure Integrity Testing	None	Container closure integrity testing was performed on the subject device using the same method and acceptance criteria as the predicate device. Results of the testing confirmed that the container closure integrity is identical between the subject and predicate devices, thereby demonstrating substantial equivalence.
Tray Lid Peel Force Testing	None	The secondary packaging of the subject device required a minor design change to accommodate the larger 10mL syringe. Tray lid peel force test results post-distribution simulation met acceptance criteria, confirming that the differences in secondary packaging do not raise different questions of safety or effectiveness.
Sterility Assurance Level	ISO 17665-1, Sterilization of healthcare products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	A sterilization validation was performed on the subject device using the same sterilization process and sterilization parameters as the predicate device. Validation results confirmed that the Sterility Assurance Level (SAL) is identical for both devices (10^{-6}), thereby demonstrating substantial equivalence.
LAL Testing	USP <85>, Bacterial Endotoxins USP <161>, Transfusion and Infusion Assemblies and Similar Medical Devices	LAL testing was performed on the subject device using the same method and acceptance criteria as the predicate device. Results of the testing confirmed that the LAL level is identical between the subject and predicate devices, thereby demonstrating substantial equivalence. Additionally, LAL testing will be performed on each lot prior to final product release.
Distribution and Post-Distribution Testing	D7386-16, ASTM Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems	Post-distribution testing was performed on the subject device using the same method and acceptance criteria as the predicate device. Results of the testing confirmed that package integrity is identical between the subject and predicate devices, thereby demonstrating substantial equivalence.

Test Description	Conforming Standard(s)	Conclusion in Support of Substantial Equivalence
Accelerated and Post-Accelerated Aging Studies	F1980-16, ASTM Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Post-accelerated aging testing was performed on the subject device using the same method and acceptance criteria as the predicate device. Results of the testing was identical between the subject and predicate devices, thereby demonstrating substantial equivalence.

VIII. CONCLUSIONS

Based on the results of the non-clinical performance testing conducted on the subject device, it has been concluded that the proposed EverLift™ Submucosal Lifting Agent is as safe and effective and performs as well as the legally marketed predicate device (K191923). The similar indications for use, intended use, technological characteristics, and performance characteristics for the proposed EverLift™ Submucosal Lifting Agent 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, the EverLift™ Submucosal Lifting Agent is substantially equivalent to the predicate device.