November 3, 2020

Micro-Tech (Nanjing) Co., Ltd.
Sally He
RA Engineer
NO. 10 Gaoke Third Road
Nanjing, Jiangsu 210032
CHINA

Re: K200071
Trade/Device Name: Blue Beacon Submucosal Injectable Solution
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: PLL
Dated: September 30, 2020
Received: October 2, 2020

Dear Sally He:

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)*
K200071

Device Name
Blue Beacon™ Submucosal Injectable Solution

Indications for Use *(Describe)*
Blue Beacon™ Submucosal Injectable Solution is indicated for submucosal lift of polyps, adenomas, early state 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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510K Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: **K200071**

1. **Date of Preparation: 2020-08-21**

2. **Sponsor Identification**

Micro-Tech (Nanjing) Co., Ltd.

No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, Jiangsu Province, PRC

Establishment Registration Number: 3004837686

Contact Person: Sally He

Position: RA Engineer

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Fax: +86-25-58350006

Email: RA.Micro-Tech@outlook.com

3. **Identification of Proposed Device**

Trade Name: Blue Beacon™ Submucosal Injectable Solution

Common Name: Submucosal Injectable Solution

Regulatory Information

Classification Name: Submucosal Injection Agent

Classification: 2

Product Code: PLL

Regulation Number: 876.1500

Review Panel: Gastroenterology/Urology

4. Identification of Predicate Device

510(k) Number: K150852

Product Name: SIC 8000 Submucosal Injection Composition

Manufacturer: Cosmo Technologies Ltd.

Note: The product named in the K150852 clearance is SIC 8000 Submucosal Injection Composition, after the product put into U.S. market, the product name has been changed to Eleview™ Submucosal Injection Composition. Therefore, the product name we purchased is Eleview™ Submucosal Injection Composition. The product to conduct substantially equivalence with proposed device is Eleview™ Submucosal Injection Composition.

Reference Device

510(k) Number: K180068

Product Name: ORISE Gel

Manufacturer: Boston Scientific Corporation

5. Indications for Use

Blue Beacon™ Submucosal Injectable Solution is indicated for submucosal lift of polyps, adenomas, early state cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

6. Device Description

Blue Beacon™ Submucosal Injectable Solution is indicated for submucosal lift of polyps, adenomas, early stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device. Under the surveillance of endoscope, in conjunction with endoscopic injection needles (Needles with a diameter equal to or greater than 23G are recommended), inject the product beneath the lesion until enough submucosal lift.

It is supplied in a 5 mL, 10ml syringe. The contents of the syringe are sterile and nonpyrogenic.

The proposed devices are moist heat sterilized to achieve the Sterility Assurance Level (SAL) of 10-6 and placed in a sterility maintenance package to ensure a shelf life of 2 years.

7. Comparison of Technological Characteristics

Blue Beacon™ Submucosal Injectable Solution is substantially equivalent in terms of both intended use, design, composition and fundamental technology to the predicate device Eleview™ Submucosal Injection Composition, which was cleared for marketing under K150852 on Sep. 03, 2015.

Comparison to predicate Devices:

Item	Proposed Device **Blue Beacon™ Submucosal Injectable Solution**	Predicate Device **Eleview™ Submucosal Injection Composition (K150852)**	Comparison to Predicate Device
Product Code	PLL	PLL	Same
Regulation No.	876.1500	876.1500	Same
Class	2	2	Same
Supplied Sterile	Yes	Yes	Same
Sterilization	Moist Heat Sterilization	Filtration and Aseptic Filling	Different
Composition	Water for Injection Sodium Hyaluronate Sodium dihydngenphoshate anhydrous Sodium phosphate dibasic, Sodium chloride Methylene blue.	Water for Injection Medium chain triglycerides, Poloxamer 188, olyoxyl-15-Hydroxystearate, Sodium chloride Methylene blue.	Similar
Indications for Use	Blue Beacon™ Submucosal Injectable Solution is indicated for submucosal lift of polyps, adenomas, early state cancers or other gastrointestinal mucosal lesions, prior to	Eleview™ Submucosal Injection Composition is intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers or other	Same

Section 5 510k summary

Item	Proposed Device **Blue Beacon™ Submucosal Injectable Solution**	Predicate Device **Eleview™ Submucosal Injection Composition (K150852)**	Comparison to Predicate Device
	excision with a snare or endoscopic device.	gastrointestinal mucosal lesions, prior to excision with a snare or other suitable endoscopic device.	
Single Use	Yes	Yes	Same
Packaging	Syringe	Ampoule	Different
Shelf Life	Two years	Two years	Same

8. Performance Data

The proposed device the Blue Beacon™ Submucosal Injectable Solution meets the requirements of AAMI ANSI ISO 10993-1:2009/(R)2013 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within A Risk Management Process”, ISO 17665-1:2006: Sterilization of health care products — Moist heat —Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

A series of bench performance tests were conducted on the proposed device and predicate device K150852, such as Appearance, Content, pH, Colorant Concentration, Viscosity, Injection Force. The bench tests performed demonstrated that the proposed device and predicate device are substantially equivalent.

The packaging of our proposed device is a pre-filled syringe, which is the same as the reference device K180068. For the testing about the pre-filled syringe, a series tests were conducted on the proposed device, such as Graduation Accuracy, Luer-lock Connection Seal Integrity, Separation Force, Tip Cap Removal Force, Seal Integrity. The tests performed demonstrated that the pre-filled syringe proposed device is qualified.

Shelf-life testing was conducted based on an accelerated aging test in accordance

with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. Two years aging test is performed to demonstrate longer stability and support the results of the accelerated aging test.

Sterilization validation was carried out in accordance with ISO17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" issued on June 16, 2016.

9. Animal Test Conclusion

The proposed device Blue Beacon™ Submucosal Injectable Solution has conducted animal test according to 21 CFR §58 (GLP Regulations) to demonstrate the safety and effectiveness.

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the Blue Beacon™ Submucosal Injectable Solution has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently cleared the Eleview™ Submucosal Injection Composition(K150852).