January 30, 2020

EndoClot Plus Co., Ltd.
% Jonathan Hu
Technical Manager
Medwheat (Shanghai) Medical Technology Co., Ltd.
Yangpu District Liaoyuan East Road Shuangyang
First Suite No. 33 Room 303
Shanghai 200093
CHINA

Re: K191254
Trade/Device Name: EndoClot
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: PLL
Dated: December 18, 2019
Received: December 26, 2019

Dear Jonathan Hu:

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.
Acting 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)*
K191254

Device Name
EndoClot

Indications for Use *(Describe)*
EndoClot® Submucosal Injection Agent is intended 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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Date Prepared: Jan 30th, 2020

510(k) Summary

[As required by 21 CFR 807.92]

1. Submitter's Information

Name of Sponsor:	EndoClot Plus Co., Ltd.
Address:	101 Room, B8 Building, 218 Xinghu Street, Suzhou Industrial Park
Contact Name:	Hendry Zhang
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Email Address:	Hendry@endoclot.com

2. Correspondent's Information

Company Name:	Med-wheat Shanghai
Correspondent Name:	Jonathan Hu
Telephone No.:	86-021-65181421
Email Address:	Jonathan.hu@medwheat.com

3. Trade Name, Common Name, Classification

Trade Name:	EndoClot®
Common Name:	Submucosal Injection Agent
Model Name:	SIA-30 (Former Name: SIS-30)
Regulation Classification	Endoscope Accessories
Regulation Number	21 CFR 876.1500
Product Code:	PLL
Classification Panel:	Gastroenterology/Urology
Device Class:	II

4. Identification of Predicate Device(s)

The identified predicates are as follow:

The SIC 8000 Submucosal Injection Composition has been cleared by FDA through 510(k) No. K150852 (Decision Date – September 3, 2015).

The Merit Syringe has been cleared by FDA through 510(k) No. K173601 (Decision Date – October 3, 2017).

5. Description of the Device

EndoClot® Submucosal Injection Agent is a sterilized single use medical device that is composed of Absorbable Modified Polymer (AMP®) particles in a plastic bottle and a spiral plunger syringe. AMP® particles are dissolved with sterile 0.9% saline to make the agent prior to use. The syringe has a Luer lock fitting to ensure a secure connection to a standard, commercially available endoscopic injection needle. The agent can be injected by rotating the plunger.

6. Intended Use/Indication for Use

EndoClot® Submucosal Injection Agent is intended 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.

7. Technological Characteristics

Endoclot® Submucosal Injection Agent is composed of Absorbable Modified Polymer (AMP®) particles in a plastic bottle and a spiral plunger syringe. Prior to use, the AMP® particles are dissolved with sterile 0.9% saline to make the agent. Then the agent is injected into the submucosal layer using our accompanied spiral plunger syringe and a standard, commercially available, endoscopic injection needle.

When comparing with the SIC8000 (**K150852**), the Endoclot® Submucosal Injection Agent has the same intended use, same classification, and same principle of operation which is operated by advancing the plunger within the barrel to inject fluids. Yet, there are also differences, such as product composition, sterilization method, packaging and shelf life. However, substantial equivalence has been demonstrated through verification.

When comparing with the Merit Syringe (**K173601**), the syringe of Endoclot® Submucosal Injection Agent has a smaller scope of intended use and most of the device material is same as that of the predicate device. The differences are the plunger material, piston material, the syringe's structure and shelf life. However, substantial equivalence has been demonstrated through verification.

8. Performance Data

Performance tests, biocompatibility tests, sterility test and animal studies were conducted to demonstrate that the Endoclot® Submucosal Injection Agent and the predicate device are substantially equivalent.

According to the performance tests, the properties (pH, density, viscosity and osmolality) of the agent are close to the predicate device, and the Endoclot® Submucosal Injection Agent has better cushion-forming duration. The results demonstrated that the proposed device is substantially equivalent to the predicate device for these performance measures.

The biocompatibility tests (ISO10993-5:2009, ISO10993-6:2016, ISO10993-10:2010, ISO 10993-11:2006, OECD 471:1997, OECD 473:2014, OECD 474:2014, ASTM F756-13, USP40_NF35<85>) and sterility test (ISO 11737-2: 2009/(R)2014) in accordance to Food and Drug Administration related guidance and recognized international standards, indicated that the Endoclot® Submucosal Injection Agent is biocompatible and safe for its intended use.

Animal studies have also been conducted to support substantial equivalence claims of our product as compared to the predicate device SIC 8000 Submucosal Injection. The objective of this study was to validate the efficacy and safety of EndoClot® Submucosal Injection Agent (compared to the predicate device) for submucosal lift during EMR/ESD procedures in GI tract of a porcine model. The results demonstrated that the proposed device is safe and effective.

9. Conclusion [21 CFR 807.92(b) (3)]

The Endoclot® Submucosal Injection Agent has the same intended use, same classification, and the same principle of operation comparing with the SIC 8000 Submucosal Injection. The syringe of Endoclot® Submucosal Injection Agent has a smaller scope of intended use and almost the same material comparing with the Merit Syringe. A series of tests have been conducted to verify the safety and effectiveness of the Endoclot® Submucosal Injection Agent.

1) The performance tests demonstrated that the device meets the design specifications and is suitable for the intended use.
2) The biocompatibility tests and sterility test indicated that the Endoclot® Submucosal Injection Agent is biocompatible and safe for its intended use.
3) The animal studies demonstrated that the EndoClot® Submucosal Injection Agent is safe and effective.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, EndoClot Plus Co., Ltd. concludes that Endoclot® Submucosal Injection Agent is substantially equivalent to the predicate devices with regard to safety and effectiveness.