January 29, 2021

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 Cn

Re: K190677
Trade/Device Name: EndoClot
Regulation Number: 21 CFR 878.4456
Regulation Name: Hemostatic Device For Intraluminal Gastrointestinal Use
Regulatory Class: Class II
Product Code: QAU
Dated: January 29, 2019
Received: March 15, 2019

Dear Mr. 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,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K190677

Device Name
EndoClot® Polysaccharide Hemostatic System

Indications for Use *(Describe)*
EndoClot® PHS is used for hemostasis of nonvariceal gastrointestinal bleeding, excluding Forrest Ia classification of bleeding.

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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Date Prepared: Jan 28th, 2021

510(k) Summary

[As required by 21 CFR 807.92]

1. Submitter's Information

Name of Sponsor:	EndoClot Plus Co., Ltd.
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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/Device Name:	Polysaccharide Hemostatic System
Mode Name:	EPK2302, EPK2303, EPK2305
Regulation Classification	878.4456
Product Code:	QAU
Classification Panel:	General & Plastic Surgery
Device Class:	II

4. Identification of Predicate Device(s)

The identified predicates within this submission are as follows:

The Hemospray® Endoscopic Hemostat (Hemospray®) has been cleared by FDA through De Novo No. DEN170015 (Date: May 7, 2018).

The EndoClot® Applicator has been cleared by FDA through 510(k) No. K162197 (Date: January 18, 2017).

5. Description of the Device

EndoClot® Polysaccharide Hemostatic System (EndoClot® PHS) is a sterilized single use medical device that is composed of Absorbable Modified Polymer (AMP®) particles in a PE bellow and an EndoClot® Applicator (K162197). The device contains no human or animal components. AMP® particles are biocompatible, non-pyrogenic and derived from plant starch.

6. Intended Use/Indication for Use

EndoClot® PHS is used for hemostasis of nonvariceal gastrointestinal bleeding, excluding Forrest Ia classification of bleeding.

7. Technological Characteristics

EndoClot® PHS is composed of Absorbable Modified Polymer (AMP®) particles in a PE bellow and an EndoClot® Applicator (K162197). AMP® particles are delivered through a catheter inserted through the working channel of an endoscope which provides access to the bleeding site.

When compared with Hemospray® (DEN170015), EndoClot® PHS has the same intended use but with reduced indications for use. They are with the same classification and same application technique that the particles are delivered by gas source and through a catheter inserted through the working channel of an endoscope which provides access to the bleeding site. Yet, there are also multiple dimensions are different, which are hemostatic particles and packaging. However, these different parts have been verified to be substantial equivalent.

When compared with EndoClot® Applicator (K162197), the applicator of EndoClot® PHS is identical with EndoClot® Applicator (K162197).

8. Performance Data

Performance tests, biocompatibility tests, chemical characterization, sterility test and in vivo animal studies were conducted to demonstrate that Endoclot® PHS and the predicate devices are substantially equivalent.

According to the performance tests, the properties (Pressure of Gas Source, Spray Pattern, Delay Time and Powder Feeding Rate, Water Absorbency and pH) of EndoClot® PHS are similar to or better than the predicate device Hemospray®. The results demonstrated that the proposed device is substantially equivalent to the predicate device for these performance measures.

The biocompatibility tests (Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Pyrogen, Subacute Systemic Toxicity, Genotoxicity, Hemocompatibility and Endotoxins), chemical characterization and sterility test in accordance to Food and Drug Administration related guidance and recognized international standards (ISO10993-5:2009, ISO10993-10:2010, ISO10993-11:2017, ISO10993-18:2020, OECD 471:1997, OECD 473:2016,

OECD 474:2016, ASTM F756-17, USP42_NF37<85> and ISO11737-2:2009/(R)2014), indicated that Endoclot® PHS is substantially equivalent to the predicate.

In vivo animal studies have also been conducted to support the substantial equivalence claims of our product as compared to the predicate device Hemospray®. The objective of the study was to validate the efficacy and safety of EndoClot® PHS (compared to the predicate device) in a swine model for gastrointestinal bleeding control. The results demonstrated that the proposed device is substantially equivalent to the predicate.

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

EndoClot® PHS has a reduced scope of intended use, with the same classification and application technique compared with Hemospray® (DEN170015). The applicator of EndoClot® PHS is identical with EndoClot® Applicator (K162197).

A series of tests were conducted to verify the safety and efficacy of Endoclot® PHS:

1) The performance tests demonstrated that the proposed device meets the design specifications and is suitable for the intended use.

2) The biocompatibility tests, chemical characterization and sterility test indicated that the proposed device is substantially equivalent to the predicate.

3) The in vivo animal studies demonstrated that the proposed device is substantially equivalent to the predicate.

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® PHS is substantially equivalent to predicate devices.