DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 18, 2017

EndoClot Plus Co., Ltd.
% Mr. Jonathan Hu
Technical Manager
Med-wheat (Shanghai) Medical Technology Co., Ltd.
Yangpu District, Liaoyuan East Road, Shuangyang
First Suite No.33 Room 303
Shanghai, China 200093 CN

Re: K162197
Trade/Device Name: EndoClot
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 15, 2016
Received: December 22, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162197

Device Name
disposable applicator

Indications for Use *(Describe)*
The EndoClot® Applicator is intended to assist the delivery of a powdered hemostatic agent to the treatment site in endoscopic surgeries.

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: Dec 15th, 2016

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 Name:	EndoClot® Applicator
Mode Name:	EA230
Regulation Classification	Endoscope Accessories
Product Code:	GCJ
Classification Panel:	Gastroenterology/Urology
Device Class:	II

4. Identification of Predicate Device(s)

The identified predicates within this submission are as follows:

The MEDAFOR DIRECT Gas-Assisted Application System have been cleared by FDA through 510(k) No. K123325 (Decision Date – Jan 24, 2013).

5. Description of the Device

EndoClot® Applicator is a medical device composed of applicator (catheter, gas/powder mixing chamber), connecting tube and gas filter, with a tube connecting to gas source in hospital. The device has good biocompatibility. By combining with external gas source, it can deliver the powdered hemostatic agent to the treatment site in endoscopic surgical procedures.

6. Intended Use/Indication for Use

The EndoClot® Applicator is intended to assist the delivery of a powdered hemostatic agent to the treatment site in endoscopic surgeries.

7. Technological Characteristics

The working situation and environment of EndoClot® Applicator is the same as that of the MEDAFOR DIRECT Gas-Assisted Application System, the technological characteristics of this product is designed to make same as that of the equivalence product. It applies EO sterilization method, which is also same as that of SE product.

A comparison of technological characteristics is provided in the following table:

Technological Characteristics	Endoclot Applicator	MEDAFOR DIRECT Gas-Assisted Application System in K123325
Product Code	GCJ	GCJ
Intended Use	The EndoClot® Applicator is intended to assist the delivery of a powdered hemostatic agent to the treatment site in endoscopic surgeries.	The device is intended to assist the delivery of a powdered hemostatic agent to the treatment site in surgical procedures including endoscopic surgeries, using a 5 mm or larger trocar.
Product Structure	Applicator(Catheter, gas/powder mixing chamber), connecting tube, gas filter	applicator, tubing set
Applicator	PTFE, PP	PTFE, PP
Connecting Tube	PVC	PVC
Gas Filter	styrene–butadienecopolymer	/
Shelf Life	3 years	3 years
Sterilization Method	EO sterilization	EO sterilization
Packaging	Tyvek and PETG	Tyvek and PETG

8. Discussion of Non-clinical Testing

The EndoClot® Applicator has been conducted related non-clinical tests to identify the substantial equivalence from the predicate device. The tests include the concerning of the biocompatibility, sterility and performance, which contains the standards including ISO10993-5:2009, ISO10993-10:2010, ISO10993-11:2006, ASTM F756-13, ISO11607-1:2006.

9. Substantial Equivalence

The EndoClot® Applicator has taken the biocompatibility, sterility and performance testing into concern in accordance to Food and Drug Administration related guidance and recognized international standards. Test data and report information are included in this submission.

10. Conclusion

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 disposable applicator is substantially equivalent to predicate devices with regard to safety and effectiveness.