May 21, 2025

Finemedix Co., Ltd.
% Woo Seok Jeong
Manager
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
Korea, South

Re: K242857
Trade/Device Name: ClearHemograsper
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KGE
Dated: April 24, 2025
Received: April 24, 2025

Dear Woo Seok Jeong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SIVAKAMI VENKATACHALAM -S

for
Shanil Haugen
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242857

Device Name

ClearHemograsper

Indications for Use *(Describe)*

ClearHemograsper has been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.

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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510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 19, 2024

1. Applicant / Submission Sponsor

FINEMEDIX CO., LTD.
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2. Submission Correspondent

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Tel: +82-10-7194-5723
Email: ws.jeong@kmcerti.com

3. Device Identification

Trade/Proprietary Name: ClearHemograsper
Common Name: Endoscopic Hemostasis Forceps
Classification Regulation: 21CFR 876.4300
Product Code: KGE
Device Class: 2

4. Predicate Devices

	Predicate Device #1
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.
Trade Name	Electrosurgical Hemostatic Forceps Series
510(k) number	K062517

5. Description

ClearHemograsper is a monopolar endoscopic instrument intended to coagulate or to perform hemostasis using high-frequency current within the digestive tract.

It can assist in endoscopic surgical procedures such as ESD (Endoscopic Submucosal

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Dissection). ClearHemograsper consists a Slider for opening or closing the Jaw, a Catheter Tube which is a part passing through the working channel of endoscope, a pair of Jaw for catching the bleeding site and for delivering high-frequency current, a plug for connecting with high frequency transmission equipment, and an irrigation port for removing foreign substances by injecting distilled water or saline solution. It is available in various working lengths.

6. Indications for use

ClearHemograsper has been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.

7. Substantial Equivalence

The ClearHemograsper is substantially equivalent to the predicate device, Electrosurgical Hemostatic Forceps Series. (K062517, OLYMPUS MEDICAL SYSTEMS CORP.). The following comparison table is presented to demonstrate substantial equivalence.

	Subject Device FINEMEDIX Co,. Ltd. ClearHemograsper	**Predicate Device OLYMPUS MEDICAL SYSTEMS CORP. Electrosurgical Hemostatic Forceps Series (K062517)**	**Similarities And Differences**
Product Code	KGE	KGE	Same
Regulation No.	876.4300	876.4300	Same
Class	2	2	Same
Indications for use	ClearHemograsper has been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.	This instrument has been designed to be used with Olympus endoscopes to cauterize, coagulate and perform hemostasis using high-frequency current within the digestive tract.	Same
Supplied in Sterile	Yes	Yes	Same
Sterilization	EO Sterilized, SAL:10^{-6}	EO Sterilized, SAL:10^{-6}	Same
Shelf Life	Three years	Three years	Same
Main Material	Stainless steel, Polytetrafluoroethylene	Stainless steel, Polyethylene	Similar. The minor gap does not affect the performance of the product, and the safety has been proven by ISO 10993-1 test reports.
Configuration	Jaws, Tube, Plug, Slider	Jaws, Tube, Plug, Slider	Same
Working length	1650mm ~ 2300mm	1650mm ~ 2300mm	Same

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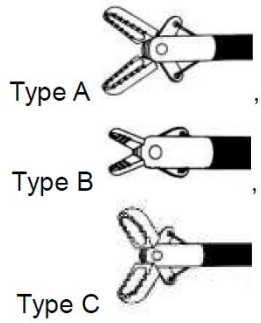
Jaws Type	Type 1  Type 2 	Type A Type B Type C 	Same
Maximum Diameter	≤2.8 mm / ≤3.2 mm	≤2.75 mm / ≤3.1 mm	Similar. The minor gap does not affect the performance and safety of the product.
Energy Used/Delivered	Monopolar Radio Frequency Current.	Monopolar Radio Frequency Current.	Same
Rated High-Frequency Voltage	COAG: 2500 Vp (5000 Vp-p)	COAG: 2900 Vp (5800 Vp-p)	Different
Biological Performance	Conform to ISO 10993-1	Conform to ISO 10993-1	Same
Electrical Safety and Electromagnetic Compatibility	Conform to: IEC60601-1 IEC 60601-1-2 IEC 60601-2-2 IEC 60601-2-18	Conform to: IEC60601-1 IEC 60601-1-2 IEC 60601-2-2 IEC 60601-2-18	Same
Single Use	Yes	Yes	Same

Technical Characteristics

1) Same Points between subject device and predicate device

Item	Description
Product Code	The product code is same between subject device and predicate device.
Regulation No.	The regulation number is same between subject device and predicate device.
Class	The class is same between subject device and predicate device.
Indications for use	The indications for use is same between subject device and predicate device.
Supplied in Sterile	The supplied in sterile is same between subject device and predicate device.
Sterilization	The sterilization is same between subject device and predicate device.
Shelf Life	The shelf life is same between subject device and predicate device.
Configuration	The configuration is same between subject device and predicate device.
Working Length	The working length is same between subject device and predicate device.
Jaws Type	The jaws type are same between subject device and predicate device.
Energy Used/Delivered	The energy used/delivered type is same between subject device and predicate device.
Biological Performance	The biological performance is same between subject device and predicate device.
Electrical Safety and Electromagnetic Compatibility	The electrical safety and electromagnetic compatibility is same between subject device and predicate device.
Single Use	The subject device and predicate device are single used device. It is same.

2) Different Points between subject device and predicate device

Item	Description
Main Material	The main materials of subject device are “Stainless steel, Polytetrafluoroethylene” and predicate device is “Stainless steel, Polyethylene”. We conducted biocompatibility test for subject device, the results show that these differences do not raise different questions of safety and effectiveness. (The biocompatibility test report is attached in this submission).
Maximum Diameter	The maximum diameter of subject device is “2.8 mm and 3.2 mm” and predicate device is “2.75 mm and 3.1 mm”. The difference in maximum diameter is within 5%, these differences do not raise different questions of safety and effectiveness.
Rated High-Frequency Voltage	The rated high-frequency voltage of subject device is “2,500 Vp” and predicate device is “2,900 Vp”. We conducted IEC 60601-2-2 test and Hemostatic Performance test for subject device, the results show that these differences do not raise different questions of safety and effectiveness. (The biocompatibility test report is attached in this submission).

8. Biocompatibility

The biocompatibility tests of patient indirect contact part (Jaw and Catheter Tube) were performed in accordance with the following FDA recognized standards.

- ISO 10993-1: 2018, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009, Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2023, Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017, Biological evaluation of medical devices -Part 11: Tests for systemic toxicity
- ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation
- FDA Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process"

9. Sterility

The Duoblade is provided sterile, intended to be single-use. This product is EO-Sterilization in accordance with ISO 11135.

The sterilization test was performed in accordance with the following FDA recognized standards.

- ISO 11135:2014: Sterilization of health-care products -Ethylene oxide -Requirements for the development, validation and routine control of a sterilization process for medical device
- ISO 10993-7:2008: Biological evaluation of medical device-Part7 Ethylene oxide sterilization residuals

10. Shelf Life

The shelf life of the subject device is 3 years.

The validation report of the subject device shows that the difference in the shelf life does not influence the quality performance of the packaging based on the result of confirmation of physical and chemical stability and effectiveness through accelerated aging test of the samples. The validation report is provided in this submission file.

The shelf life method has been validated in accordance with the following standards.

- ASTM F1980-16: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible BarrierMaterials
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices –Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019, Packaging for terminally sterilized medical devices –Part 2: Validation requirements for forming, sealing and assembly processes

11. Electromagnetic Compatibility (EMC) and Electrical Safety

The Electromagnetic Compatibility (EMC) and Electrical Safety tests were performed in accordance with the following FDA recognized standards.

- IEC 60601-1:2005/A1:2012/A2:2020, Medical electrical equipment -Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 /A1:2013/A2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-2:2017/A1:2023, Medical electrical equipment -Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances -Requirements and tests

12. Performance Test

The following performance tests were performed.

1) Dimension Test
2) Rotatable Performance Test
3) Pushability Test
4) Actuation Test
5) Tensile Strength Test
6) Output Value Test
7) Hemostatic Performance Test
8) Removal of the High-Frequency Plug Test
9) Short Circuit Test
10) Catheter Tube Temperature Test

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13. Clinical Test

No clinical studies were considered for this submission.

14. Conclusion

In comparing between the subject device and the predicate device, there are the same Product Code, Regulation Number, Class, Indications for use, Supplied in Sterile, Sterilization, Shelf Life, Configuration, Working Length, Jaws Type, Energy Used/Delivered, Biological Performance, Electrical Safety and Electromagnetic Compatibility and Single Use.

Although the Main Material, Maximum Diameter and Rated High-Frequency Voltage are difference, these differences do not raise different questions of safety and effectiveness.

Therefore, the subject device is substantially equivalent to the predicate device.