June 23, 2022

Incore Co., Ltd.
% Seon-Mi Kim
Consultant
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
KOREA, SOUTH

Re: K213338
Trade/Device Name: Core-clip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: May 20, 2022
Received: May 23, 2022

Dear Seon-Mi Kim:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213338

Device Name
CORE-CLIP

Indications for Use *(Describe)*
It is intended to be used with FDA-cleared endoscope for endoscopic clip placement within the gastrointestinal tract. It is indicated to be used for
(1) Endoscopic marking
(2) Hemostasis for
(a) Mucosal/sub-mucosal defects < 3cm
(b) Bleeding ulcers
(c) Arteries < 2 mm
(d) Polyps < 1.5 cm in diameter
(e) Diverticula in the colon
(3) As a supplementary method, closure of GI tract luminal perforations <20 mm that can be treated conservatively

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
(K213338)

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

Date: May 19, 2021

1. INFORMATION

1.1 Submitter Information

- Submitter Name: INCORE Co., Ltd.
- Address
  : 11, Hyeoksin-daero 78-gil, Dong-gu, Daegu, Republic of Korea
- Telephone Number: +82-2-866-3514
- Fax: +82-2-6919-1346

1.2 Contact Person

- Name: Seon-mi Kim (Consultant / KMC, Inc.)
- Address: Rm. No. 1709, 123, Digital-ro 26-gil, Guro-gu, 08390, Republic of Korea
- Telephone Number: +82-70-8965-5554
- Fax: +82-2-2672-0579
- E-mail: ctrl903@kmcerti.com

2. DEVICE INFORMATION

2.1 Trade Name / Proprietary Name: CORE-CLIP

2.2 Common Name: Disposable endoscope clip

2.3 Product Code: PKL

2.4 Classification Regulation: 21CFR 876.4400

2.5 Device Class: Class II

2.6 Classification Panel: Gastroenterology/Urology

3. PREDICATE DEVICE

Manufacturer	Finemedix Co., Ltd.
Device Name (Trade Name)	ClearEndoclip
510(k) Number	K183021

4. OVERVIEW OF THE PEODUCT

The endoscope clip is a metallic mechanical device used in endoscopy in order to close two mucosal surfaces without the need for surgery and suturing. Its function is similar to a suture in gross surgical applications, as it is used to join together two disjointed surfaces, but, can be applied through the channel of an endoscope under direct visualization. The endoscope clip has found use in treating gastrointestinal bleeding (both in the upper and lower GI tract), in preventing bleeding after therapeutic procedures such as polypectomy, and in closing gastrointestinal perforations.

The Handle Slider and the coil are connected, and the coil and the clip are connected. When the Handle Slider is moved backward, the coil connected to the Handle Slider is pulled back, and the clip is also pulled back and the clip is closed as the clip enters the Clip Body. After the clip is completely closed, the clip will no longer be pulled back and when the threshold is reached, the Disconnection connector part will eventually break. As a result, the delivery device and the clip are completely separated, and the clip remains alone to maintain hemostasis.

5. INDICATIONS FOR USE

It is intended to be used with FDA-cleared endoscope for endoscopic clip placement within the gastrointestinal tract. It is indicated to be used for

(1) Endoscopic marking

(2) Hemostasis for

- (a) Mucosal/sub-mucosal defects < 3cm
- (b) Bleeding ulcers
- (c) Arteries < 2 mm
- (d) Polyps < 1.5 cm in diameter
- (e) Diverticula in the colon

(3) As a supplementary method, closure of GI tract luminal perforations <20 mm that can be treated conservatively

6. SUBSTANTIAL EQUIVALENCE

6.1 Comparison Table

Comparison of the technical characteristics of the subject device and predicate devices is shown in the Table of Substantial Equivalence Below

6.1.1 Indications for use

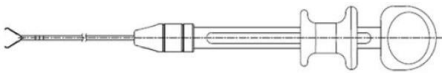
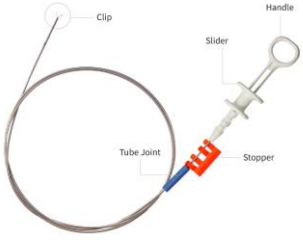
The Indications for Use Statements are compared in the tables below. It can be seen that the Indications for Use Statements of the Subject and Primary Predicate device are similar as support

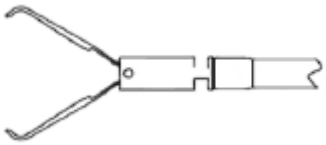
as an endoscopic clip placement within the gastrointestinal tract.

Although some indications are different between the subject device and primary predicate device, the test results of bench test of the rest of the products demonstrated that this difference does not raise new safety or effectiveness concerns for the provided intended use.

Descriptive Information	**Subject Device (K213338)**	**Primary Predicate Device (K183021)**
Manufacturer	Incore, Co., Ltd.	Finemedix Co., Ltd.
Product Name	Core-Clip	ClearEndoclip
Regulation	21CFR 876.4400	21CFR 876.4400
Product Code	PKL	PKL, FHN, MND
Indications for Use	It is intended to be used with FDA-cleared endoscope for endoscopic clip placement within the gastrointestinal tract. It is indicated to be used for (1) Endoscopic marking (2) Hemostasis for (a) Mucosal/sub-mucosal defects < 3cm (b) Bleeding ulcers (c) Arteries < 2 mm (d) Polyps < 1.5 cm in diameter (e) Diverticula in the colon (3) As a supplementary method, closure of GI tract luminal perforations <20 mm that can be treated conservatively	ClearEndoclip is intended to be used with FDA-cleared endoscope for endoscopic clip placement within the gastrointestinal tract. It is indicated to be used for (1) Endoscopic marking (2) Hemostasis for (a) Mucosal/sub-mucosal defects < 3cm (b) Bleeding ulcers (c) Arteries < 2 mm (d) Polyps < 1.5 cm in diameter (e) Diverticula in the colon (3) Anchoring to affix jejunal feeding tubes to the wall of the small bowel (4) As a supplementary method, closure of GI tract luminal perforations <20 mm that can be treated conservatively

6.1.2 Technical

Descriptive Information	**Subject Device (K213338)**	**Primary Predicate Device (K183021)**
Picture		

Clip Picture		
Sterilization	Ethylene Oxide	Ethylene Oxide
Shelf Life	3 years	3 years
Target	Gastrointestinal mucosal/submucosal	Gastrointestinal mucosal/submucosal
Single use / Re-use	Single-use	Single-use
Clip opening width (Unit: mm)	11mm	9mm / 11mm / 13mm / 16mm
Handle Controlled Clip Rotation	360°	360°
Coil length (Unit: cm)	160cm, 230cm	165cm, 230cm
Outer Diameter (Unit: mm)	2.4mm	2.6
Material	Clip: Stainless-steel Sheath Coating Coil: Polypropylene, Stainless-steel Handle: ABS	Clip: Stainless-steel Sheath Outer: HDPE Stopper: Polypropylene
MR Environment	MR Unsafe	MR Unsafe

6.2 Comparison Conclusion to predicate device

The subject device is substantially equivalent to the predicate device with respect to indications for use, technology and construction. The differences between the predicate devices and the subject devices are minor and any risks have been mitigated through testing.

7. NON-CLINICAL DATA

As part of demonstrating substantial equivalence of the CORE-CLIP to the predicate device, INCORE Co., Ltd. conducted performance testing on the subject device. Although there are slightly different points such as dimension or material, it does not impact the ability to determine substantial equivalence of the subject device because the substantial equivalence of performance for CORE-CLIP is demonstrated by the following verification and validation data to demonstrate the safety and performance effectiveness.

- Sterilization
  CORE-CLIP is sterilized by EO GAS on the sterilization process.
  A. EO Gas Sterilization Validation Report in accordance with ISO 11135:2014, ISO 11138-1:2017, ISO 11138-2:2017, ISO 11737-1:2018, ISO 11737-2:2019, EN ISO 10993-7:2008/AMD:2019 and AAMI TIR28: 2009/(R)2013
- Packing Validation with shelf-life and integrity test
  Stability and the effectiveness of packaging as sterilized product by evaluation in process of time and performance of packaging material according to the ISO 11607-1:2019, ISO 11607-2:2019, ASTM F1980, USP39 <71>, ASTM F88, ASTM F1929
- Biocompatibility Test
  The biocompatibility tests were performed to protect patients from undue risks arise from biological hazards associated with materials of manufacture and final device. The tests were performed in accordance with ISO 10993-1, ISO 10993-5, -10, -3, -11, -6, and FDA Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".
- Performance
  The following tests were performed to assess effectiveness of the bench product performance. The tests were performed in accordance with in house hold standard caused by predicate device to demonstrate substantial equivalence between subject device and predicate device.

Test Item	Test Item
Rotation test	Tensile strength (Between Clip and Coil wire)
Repeat open/close test	Tensile strength (Between Coil and Handle)
Clamping retention time	

The mechanical properties tests were performed by being based on each product different properties and dimensions.

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

8. Clinical and Animal Test

In vivo animal testing was performed for the adhesion safety and hemostatic performance to support indication for use

9. Conclusion

The comparison between the subject device and the predicate device shows that the general information, some technical and material information are the same. Although there are some differences, the bench performance test reports are supported to the substantial equivalence of the subject device, the bench performance test reports are provided to demonstrate substantial equivalence of the subject device. Therefore, we conclude that the different characteristics do not raise different questions of safety and effectiveness, and thus the subject devices are substantially equivalent to the predicate device