November 21, 2022

Incore Co., Ltd.
Jae-Hun Lee
Department head of Regulatory Affairs
11, Hyeoksin-daero, 78-gil, Dong-gu
Daegu, 41072
KOREA, SOUTH

Re: K220846
Trade/Device Name: Core-Snare
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: FDI
Dated: March 15, 2022
Received: March 23, 2022

Dear Jae-Hun Lee:

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,

Sivakami Venkatachalam -S

for
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)*
K220846

Device Name
CORE-SNARE

Indications for Use *(Describe)*
The CORE-SNARE is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI 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.

Section 5 - 510(K) Summary

In accordance with the Food and Drug Adminstration Rule to implement provisions of the Safe Medical Device Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the CORE-SNARE.

Ⅰ. Submitted by

Company Name : INCORE CO.,LTD.
Company Address : 11, Hyeoksin-daero 78-gil, Dong-gu, Daegu, Republic of Korea

Contact Person : Mr. Jae-Hun, Lee
Department head of Regulatory Affairs

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Date of Preparation : March 15, 2022

Ⅱ. Device

Trade of Device : CORE-SNARE

Model : IC-SN0210, IC-SN0215, IC-SN0310, IC-SN0313, IC-SN0315, IC-SN0324, IC-SN0330, IC-SN0410, IC-SN0413, IC-SN0415, IC-SN0424, IC-SN0430, IC-SN3310, IC-SN3313, IC-SN3315, IC-SN3324, IC-SN3330, IC-SN0410CR, IC-SN0415CR, IC-SN0424CR, IC-SNR0210, IC-SNR0215, IC-SNR0310, IC-SNR0313, IC-SNR0315, IC-SNR0324, IC-SNR0330, IC-SNR0410, IC-SNR0413, IC-SNR0415, IC-SNR0424, IC-SNR0430, IC-SNR3310, IC-SNR3313, IC-SNR3315, IC-SNR3324, IC-SNR3330, IC-SNR0410CR, IC-SNR0415CR, IC-SNR0424CR

Common or Usual Name : Disposable electrically-operated medical snare
Classification Name : Endoscopic Electrosurgical Unit and Accessories
Device Product Code : FDI
Review Panel : Gastroenterology/Urology
Regulation Number: 21 CFR 876.4300 Endoscopic Electrosurgical Unit and Accessories.
Regulatory Class : Class II

Ⅲ. Predicate Device

Device Name : ClearGrasp Snare
Manufacturer : Finemedix Co. Ltd
510(K) Number : K183289
Classification Name : Endoscopic Electrosurgical Unit and Accessories
Product Code : FDI
Regulatory Class : Class II
Regulation Number: 21 CFR 876.4300 Endoscopic Electrosurgical Unit and Accessories.

The predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

Ⅳ. Device Description

The CORE-SNARE is a disposable device for cuts out and removes the tissues such as polyps after entering a site to be treated during endoscopic procedures.
The device consists of Snare-loop connected with catheter tube and Catheter tube pass through operating channel of endoscope and Handle connected with snare through the catheter tube. It is available in various sizes and working lengths.
Users can choose an Oval or a Crescent or Diamond type based on their preference and the characteristic of the lesion. The loop sizes can be chosen in accordance with the size of the lesion and the rotational type helps approaching and grasping the lesion.
When connected to an electrosurgical generator and activated, the loop delivers a monopolar electrical current to the surgical site.
The proposed product is packed in a sealed pouch following EO Sterilization (SAL 10^{-6}). This device is supplied sterile for single-patient use and shall be not reused or re-sterilized.

Ⅴ. Indications for Use

The CORE-SNARE is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

Ⅵ. Comparison of Technological Characteristics with predicate device

The CORE-SNARE has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Finemedix CO.,Ltd's ClearGrasp Snare, K183289. the differences between the proposed device and the predicated devices do not raise any questions regarding its safety and effectiveness. the differences are listed in the table below.
The following tests evaluate the substantial equivalence of the subject device through the performance test applying the same standard as the predicate device.
Performance testing such as appearance, dimension, continuity, tensile strength test of electrode cable, withstand voltage, high frequency leakage current test of electrode cable according to IEC 60601-2-2:2017 and ANSI/AAMI HF18:2001. The test results show that the subject device is substantially equivalent to the predicate device.

Table 1 : Comparison to Predicate Device

Item	**Proposed Device** CORE-SNARE	**Predicate Device** ClearGrasp Snare	**Substantial Equivalence**
Classfication regulation	21 CFR 876.4300	21 CFR 876.4300	Same
Classification and Code	Class Ⅱ, FDI	Class Ⅱ, FDI	Same
Device Classfication Name	Endoscopic Electrosurgical Unit and Accessories	Endoscopic Electrosurgical Unit and Accessories	Same
510(K) number	K220846	K183289	-
Indications for Use	The CORE-SNARE is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.	The ClearGrasp Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.	Same
Configuration	Loop, Catheter Tube, Handle(Slider, Body)	Loop, Catheter Tube, Handle, Slider, Plug	Similar

Material	Loop	SUS 304	SUS 304	Same
	Catheter Tube	PTFE	PTFE	
	Handle	ABS	ABS	
Shape of Loop		Oval and Crescent and Diamond	Oval and Crescent	Similar
Working Length		2200, 2400mm	1600, 1800, 2200, 2400mm	Similar
Loop Size		10, 15, 24, 30mm	6,10,13,15,24,30 mm	Similar
Rotational/Non-Rotational		Both	Both	Same
Sterilization		EO Sterilization	EO Sterilization	Same
Single Use		Yes	Yes	Same
Used with Electrosurgical Unit		Yes	Yes	Same

Ⅶ. Non-clinical testing data

1) Sterility

A sterility validation was completed following ISO 11135 requirements to demonstrate a 10^{-6} SAL. And the proposed device meets the requirements of ISO 10993-7 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals”
The Sterility test is tested with a direct method.
No evidence of microbial growth is found, the test article to be examined complies with sterility test.

2) Biocompatibility Testing

Biocompatibility testing has been performed in accordance with ISO 10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”

The CORE-Snare is considered tissue contacting for a duration of less than 24 hours.

The proposed device passed all biocompatibility tests.
In accordance to ISO10993-1, the following biocompatibility tests were performed : Cytotoxicity, Maximization Sensitization, Intractutaneous Reactivity, Acute Systemic Toxicity, Pyrogen test.

3) Performance Testing

(1) Demension test

When measured by vernier calipers, the tolerance of the nominal size should be ±10 % of the stndard. For the dimensional test, all dimensions of the core-snare non-rotation type product were measured. As a result of the measurement, it was confirmed that all dimensional values do not exceed the tolerance of ±10%. Therefore, the CORE-SNARE meets the performance required by demension test.

(2) Tensile strength test

① Electrode Cable

The tensile strength test method for Electrode Cable was performed in accordance with ANSI/AAMI HF 18 (2001) 4.2.5.5, and according to method, Electrode cables and connecting parts shall not be damaged from 40 N pulling and 0.64 J impact.
The proposed device was tested, and there was no damaged from 40 N pulling and 0.64 J impact.
Therefore, the CORE-SNARE meets the performance required by tensile strength of electrode cable.

② Inner rope-cutting wire

The tensile strength (inner rope-cutting wire) was tested as follows.
The cutting knife is cut out from the sheath by manipulating the handle. The inner rope and the cutting wire are cut at a position of about 15cm from the end to make a specimen, and the specimen is pulled at a rate of 1.0 in/min.
Under the conditions of the above method, the strength between the inner rope and the cutting wire should be not less than 15 lbs.
The proposed device was tested, and It was confirmed the strength is more than 15 lbs.
Therefore, the CORE-SNARE meets the performance required by tensile strength of

inner rope-cutting wire.

③ Catheter sheath-handle

The tensile strength (catheter sheath-handle) was tested as follows.
After manipulating the handle, pull out the cutting knife out of the sheath, cut the sheath and cable at 2 inches of the distal end of the strain relief to make a specimen, and pulled at a rate of 1.0 in/min.
Under the conditions of the above method, the strength between the catheter sheath and the handle should be not less than 2 lbs.
The proposed device was tested, and there was more than 2 bs.
Therefore, the CORE-SNARE meets the performance required by tensile strength of catheter sheath-handle.

(3) Cable Withstand voltage

The main frequency withstand voltage meets the test criteria that the rate accessory voltage specified by the manufacturer of the high frequency surgical accessory must withstand a peak voltage of 1000V, large DC or Mains frequency for 5 minutes.
And the high-frequency withstand voltage must withstand for 30 seconds at high frequency voltage of 120% of the rated accessory voltage presented by the manufacturer. Maximum voltage of accessory is 920 Vp.
For the test, refer to the test method with the following IEC 60601-2-2:2011.
The proposed device was tested according to the above criteria and passed.
Therefore, the CORE-SNARE meets the performance required by Cable Withstand voltage.

(4) High Frequency leakage current test

High frequency leakage current testing has been performed in accordance with ANSI / AAMI HF 18(2001) 4.2.5.2.
The monopolar high-frequency leakage current of the electrode cable shall be not more than 3.6 dfL mA and, the connection cord shall not have worked loose nor shall it show any damage.
For multiconductor cables there shall be no short circuits betwwen individual conductors.
The proposed device was tested according to the above criteria and passed.

Therefore, the CORE-SNARE meets the performance required by High frequency leakage current test

(5) Conductive Inspection (Continuity test)

This test is performed using electrical conduction circuit system, and tips for connection with electrode tip must be electrically connected to each other.
The proposed device was tested according to the above criteria and passed.
Therefore, the CORE-SNARE meets the performance required by Conductive inspection.

4) Physical/Chemical

Extraction Test is tested accordance with In-house hold.
Test items are Appearance, pH, KMnO4 Consumption, Evaporating residue, Ultraviolet absorption, Heavy metal are acceptable level.

5) Shelf Life Test

The CORE-SNARE has a maximum shelf life of 3 years from the date of sterilization.
In compliance with the standard of ASTM F1980 ; S*tandard Guide For Accelerated Aging of Sterile Barrier System for Medical Device,* accelerated aging studies for start and three(3) years were performed to determine product integrity over its lifespan, with acceptable results. A real-time aging study is currently in process to verify the result found in the accelerated aging studies.

Ⅷ. Conclusion

The conclusion drawn from the technological characteristics is that the CORE-SNARE has been found to have a safety and efficacy profile that is substantially equivalent to the predicate device ClearGrasp Snare which is marketed for the same intended use.