December 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: K221054
Trade/Device Name: Core-Injector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK
Dated: March 22, 2022
Received: April 11, 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)*
K221054

Device Name
CORE-INJECTOR

Indications for Use *(Describe)*
The CORE-INJECTOR is to be used in conjunction with an endoscope to perform endoscopic injections, such as the treatment of esophageal and gastric varices and for submucosal dye marking in 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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-INJECTOR.

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

Contact Phone : (82) 2-866-3514
Contact Fax : (82) 2-6919-1346

Date of Preparation : March 18, 2022

Ⅱ. Device

Trade of Device : CORE-INJECTOR
Model : IC-IJ2312, IC-IJ2316, IC-IJ2318, IC-IJ2323, IC-IJ2512, IC-IJ2516, IC-IJ2518, IC-IJ2523
Common or Usual Name : Disposable endoscope injection needle
Classification Name : Endoscope and Accessories
Device Product Code : FBK
Review Panel : Gastroenterology/Urology
Regulatory Class : Class II
Regulation Number: 21 CFR 876.1500 Endoscope and Accessories

Ⅲ. Predicate Device

Device Name : INJECTION NEEDLE
Manufacturer : Micro-Tech (Nanjing)CO., Ltd.

510(K) Number : K150434
Classification Name : Endoscope and Accessories
Product Code : FBK
Regulatory Class : Class II
Regulation number : 21 CFR 876.1500

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

Ⅳ. Device Description

The CORE-INJECTOR, the disposable endoscope injection needle is a disposable device for injecting medicine and medical supplies into a mucous membrane or blood vessel to stop the bleeding or for hardening the vessel during endoscopic procedure.
The device consists of a stainless steel needle attached to sheath and handle where a syringe with solution for injection can be attached. It is available in various sizes and working lengths. The needle sizes are 23 gauge and 25 gauge, and the needle length is 4.0mm. The working length includes 1,200mm, 1,600mm, 1,800mm, 2,300mm.
The operating time is less than 1 hour. it contacts with mucosa of the human digestive tract. 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-INJECTOR is to be used in conjunction with an endoscope to perform endoscopic injections, such as the treatment of esophageal and gastric varices and for submucosal dye marking in the GI tract.

Ⅵ. Comparison of Technological Characteristics with predicate device

The CORE-INJECTOR has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Micro-Tech (Nanjing)CO., Ltd.'s INJECTION NEEDLE, K150434. 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 Tensile Strength, Needle drawing out, Leakage test, Liquidity test, Maneuverability test. 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-INJECTOR	Predicate Device INJECTION NEEDLE	**Substantial Equivalence**
Classfication regulation	21 CFR 876.1500	21 CFR 876.1500	Same
Classification and Code	Class Ⅱ, FBK	Class Ⅱ, FBK	Same
Device Classfication Name	Endoscopy and Accessories	Endoscopy and Accessories	Same
510(K) number	K221054	K150434	-
Indications for Use	The CORE-INJECTOR is to be used in conjunction with an endoscope to perform endoscopic injections, such as the treatment of esophageal and gastric varices and for submucosal dye marking in the GI tract.	The INJECTION NEEDLE is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.	Same
Configuration	Needle, Inner tube, Outer tube, Handle, Slider	Needle, Inner sheath(Tube), Outer Outer shell(tube), Handle, Luer lock	Similar Both subject and predicate device are substantially equivalent in the indications for use.
Material (Needle)	Stainless-Steel	Stainless-Steel	Same
Outer Sheath Material	Outer : Polyethylene	Outer : Thermoplastic-PTFE Polymer	Different

			This difference does not alter the suitability of the proposed device for its intended use. We conducted a biocompatibility evaluation of the device. The results show the device is safe in the aspect of biocompatibility evaluation
Disposable	Yes	Yes	Same
Gauge size	23G, 25G	19G, 22G, 25G	Similar Both subject and predicate device are substantially equivalent in the indications for use.
Needle length	4mm	4mm, 5mm, 6mm	Same
Outer Sheath Diameter	2.3mm	2.3mm	Same
Working Length	1200mm, 1600mm, 1800m, 2300mm	1800mm, 2000m, 2300mm	Similar Both subject and predicate device are substantially equivalent in the indications for use.
Sterilization	EO Sterilization (SAL 10-6)	EO Sterilization (SAL 10-6)	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	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 conducted in accordance with ISO 10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”
The CORE-INJECTOR is considered tissue contacting for a duration of less than 24 hours.
This device passed all biocompatibility tests. In accordance to ISO10993-1:2018, the following biocompatibility tests were performed : Cytotoxicity, Sensitization, Intracutaneous reactivity, Acute Systemic Toxicity, Pyrogen test.

3) Performance Testing

(1) Appearance and dimension

Performance tests such as the appearance and dimensions of the proposed device were according to the Incore's own system.

(2) Tensile strength (handle)

The product that cut to about 4 inches from the outer hub is held in a tensile taster set to 3 inches in gage length. Then, the inner hub is pulled from the outer hub at a speed of 10 in/min. Under the conditions of the above method, the inner hub should be attached to the outer hub when applying a force of 15N.
The proposed device was tested, and there was no defect after loading 15N.
The CORE-INJECTOR therefore meets the performance required by tensile strength of handle.

(3) Needle drawing test(Pull-out) (needle)

The prodcut, the inner hub is pulled from the outer hub and the inner sheath is pulled from the outer sheath by pulling on the sheath. After cutting this to about 3 inches from the crimp band, mount it with the needle facing upward in a tensile tester set to 2 inches in gauge length. Check that the needle is attached to the inner sheath with a force of 10N when pulling at a speed of 10 in/min.

Under the conditions of the above method, the needle should be attached to the inner sheath.
The proposed device was tested, and the needle attached to the inner sheath when applying a force of 10N.
Therefore, the CORE-INJECTOR meets the performance required by pull-out of needle test.

(4) Air leakage test

When observing air leakage while blocking one end of the product and applying air pressure of 50 kPa to the inside of the product for 15 seconds, there should be no air leakage.

(5) Liquidity test

Attach a syringe containing 10g of distilled water into the injection port of the injector. Then, the distilled water is injected by pushing the piston with a constant force. After receiving the distilled water ejected from the injector needle into the cylinder, measure the amount of distilled water.

(6) Maneuverability test

Check that the needle goes in when the handle slider is pulled, and the needle comes out when pushed, and check that the handle and needle operate smoothly.

(7) Elasticity test (needle)

Fix A point of the needle randomly and bend to 12° with weight and 1 minutes at B point. Under the conditions of the above method, the needle shall return after remove weight.
TThe proposed device was tested, and the needle returned to its original state when the weight was removed.
Therefore, the CORE-INJECTOR meets the performance required by elasticity test of needle.

4) Physical/Chemical

Extraction Test is tested in accordance with KP(Korean Pharmacopia)
appearance, pH, KMnO4 Consumption, Evaporating residue, Ultraviolet absorption, Heavy metal are acceptable level.

5) Shelf Life Test

The CORE-INJECTOR 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-INJECTOR has been found to have a safety and efficacy profile that is substantially equivalent to the predicate device INJECTION NEEDLE which is marketed for the same intended use.