Incore CO., LTD.
Mr. Jae-Hun Lee
Department Head of Regulatory Affairs
11, Hyeoksin-daero, 78-gil, Dong-gu
Daegu, Republic of Korea

Re: K211148
Trade/Device Name: CORE-Trocar (Nine Models)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 19, 2022
Received: May 19, 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,

for

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K211148

Device Name
CORE-Trocar, (Model : IC-TC02, IC-TC02S, IC-TC03, IC-TC03S, IC-TC05, IC-TC05S, IC-TC08, IC-TC10, IC-TC12)

Indications for Use *(Describe)*
The CORE-Trocar is a single-use medical device to have a port to insert endoscopic instruments for endoscopic procedures.

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.

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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-Trocar.

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 : June 15, 2022

Ⅱ. Device

Trade of Device : CORE-Trocar, (Model : IC-TC02, IC-TC02S, IC-TC03, IC-TC03S, IC-TC05, IC-TC05S, IC-TC08, IC-TC10, IC-TC12)
Common or Usual Name : Bladeless Endoscopic Trocar
Classification Name : Laparoscope, General & Plastic Surgery
Device Product Code : GCJ
Regulatory Class : Class II
Device Classification Panel : General & Plastic Surgery

Ⅲ. Predicate Device

Device Name : Unimicro Trocar Kit (K141594)
Manufacturer : Unimicro Medical Systems (ShenZhen) Company, Ltd.
Classification Name : Laparoscope, General & Plastic Surgery
Regulatory Class : Class II

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

Ⅳ. Device Description

The CORE-Trocar has a port to insert endoscopic instruments during endoscopic procedures. It consist of a cannula and a obturator. The Trocar is available in nine (9) models(IC-TC02, IC-TC02S, IC-TC03, IC-TC03S, IC-TC05, IC-TC05S, IC-TC08, IC-TC10, IC-TC12) and the models are divided into six (6) types according to the kinds of diameter Type : 2mm Type(IC-TC02, IC-TC02S), 3mm Type(IC-TC03, IC-TC03S), 5mm Type(IC-TC05, IC-TC05S), 8mm Type(IC-TC08), 10mm Type(IC-TC10) and 12mm Type(IC-TC12). The cannula assembly have seals(main, secondary), a valve and a stopcock. The obturator has non-bladed tip. Sterilization is done with EO gas and Sterilization Assurance Level(SAL) 10^{-6}. The seals prevent loss of CO^2 pneumoperitoneum pressure when instruments are inserted or withdrawn.

Ⅴ. Indications for Use

The CORE-Trocar is a single-use medical device to have a port to insert endoscopic instruments for endoscopic procedures.

Ⅵ. Comparison of Technological Characteristics with predicate device

There is no technical difference between the CORE-Trocar and the Unimicro Trocar Kit. Even if some test's name is a little different, the intention of the test is same.

Table 1 : Comparison to Predicate Device

Item	Proposed Device CORE-Trocar	Predicate Device Unimicro Trocar Kit
510(K) number	K211148	K141594
Classfication	21 CFR 876.1500	21 CFR 876.1500

<table>
<tr><td>regulation</td><td></td><td></td></tr>
<tr><td>Classification and Code</td><td>Class Ⅱ, GCJ</td><td>Class Ⅱ, GCJ</td></tr>
<tr><td>Device Classfication Name</td><td>Laparoscope, General & Plastic Surgery</td><td>Laparoscope, General & Plastic Surgery</td></tr>
<tr><td>Indications for Use</td><td>A single-use medical device to have a port to insert endoscopic instruments for endoscopic procedures.</td><td>Applicate in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.</td></tr>
<tr><td>Compared elements</td><td>Cannula
Tip of obturator</td><td>Cannula
Tip of obturator</td></tr>
<tr><td>Performance - Bench</td><td>Dimentsion
Insertion force
Air leakage
Seal Test
Instrument compatibility test</td><td>-</td></tr>
<tr><td>Performance test - Comparative</td><td>Seal Test
Instrument compatibility test
Obturator compatibility
Insertion & Cannula stability
Air leakage</td><td>Obturator compatibility
Insertion & cannula stability
Air leakage</td></tr>
<tr><td>Disposable</td><td>Yes</td><td>Yes</td></tr>
<tr><td rowspan="2">Dimension</td><td>Diameter : 2 ~ 12mm
<table><tr><th>Type</th><th>Diameter</th><th>Type</th><th>Diameter</th></tr><tr><td>2mm</td><td>2.45mm</td><td>8mm</td><td>8.1mm</td></tr><tr><td>3mm</td><td>3.75mm</td><td>10mm</td><td>11.8mm</td></tr><tr><td>5mm</td><td>6mm</td><td>12mm</td><td>12.9mm</td></tr></table></td><td>Diameter : 5 ~ 12mm</td></tr>
<tr><td>Length : 100 ~ 150mm
<table><tr><th>Type</th><th>Length</th></tr><tr><td>2mm, 3mm, 5mm</td><td>100.5mm, 125.5mm</td></tr><tr><td>8mm</td><td>130mm</td></tr><tr><td>10mm, 12mm</td><td>149.5mm</td></tr></table></td><td>Length : 70 ~ 120mm</td></tr>
<tr><td>Sterilization</td><td>EO Sterilization (SAL 10^{-6})</td><td>EO Sterilization (SAL 10^{-6})</td></tr>
<tr><td rowspan="3">Combination list</td><td>Bladeless Trocar</td><td>Bladeless Trocar</td></tr>
<tr><td>/</td><td>Auto-Locking Trocar</td></tr>
<tr><td>/</td><td>Hasson Trocar</td></tr>
</table>

Ⅶ. Test summary

(1) Safety Test

1) Sterility

A sterility validation was completed following ISO 11135 requirements to demonstrate a 10^{-6} SAL.
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-Trocar 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, Maximization Sensitization, Irritation/Intractutaneous Reactivity, Acute Systemic Toxicity, Pyrogen.

(2) Performance test – bench

Test	Subject device	Criteria	Standard	Result
Dimension	CORE-Trocar (All model)	The tolerance of the nominal size should be ±10 % of the stndard.	Internal standard	Pass
Insertion force	CORE-Trocar (IC-TC12)	1.5kgf ≥ Insertion force	Internal standard	Pass
Air leakage	CORE-Trocar (IC-TC12)	No air leakage	Internal standard	Pass
Seal Test	CORE-Trocar (IC-TC05,IC-TC12)	No air leakage	Internal standard	Pass
Instrument	CORE-Trocar	no crash, no damage, no	USP 38, <661>	Pass

compatibility test		(IC-TC05, IC-TC12)	strong friction	Physicochemical Test	
Extractable Substance	Nonvolatile Residue	CORE-Trocar (IC-TC03)	Residue gap, below 15mg		Pass
	Residue on Ignition		Residue gap, below 5 mg		Pass
	Buffering Capacity		Not be darker		Pass
	Heavy Metal		Titrant gap (or sum), below 10mL		

1) Dimension

- Test methods

When measured by vernier calipers, the tolerance of the nominal size should be ±10 % of the stndard.

- Acceptance Criteria

The tolerance of the nominal size should be ±10 % of the stndard.

2) Insertion force

- Test methods

When pushing the trocar into the cannula(150mm/min), apply a force below the test standard to verify that it passes through the main and secondary seals. Under the conditions of the above method, the insertion force shall be not more than 1.5 kgf.
The Insertion force of CORE-Trocar was tested, and a force averaged 0.964 kgf (min. 0.738 and max. 1.095) was found to comply with the requirements required.
The CORE-Trocar therefore meets the performance required by insertion force test.

- Acceptance Criteria

1.5kgf ≥ Insertion force

3) Air leakage

- Test methods

When sealing the valve and applying air at a pressure of 15 mmHg at the bottom of the cannula body, check for air leaks at the top of the test article or at the valve. Under the conditions of the above method, the test article shall be no air leakage.
The air leakage of CORE-Trocar was tested and, there is no air leakage.
The CORE-Trocar therefore meets the performance required by air leakage test.

- Acceptance Criteria
No air leakage

4) Seal Test

- Test methods
Connect a pressure tester at the botton of the each canulla. and set to test leakage at a pressure fo 17mmHg(0.329psi). Test initially with the trocar ports empty, and then with 2 different diameters(2mm and 12mm) metal probes traversing the seal to simulate small and large laparoscopic instrument insertion. repeat traversing 20 and check the leakage.
The seal leakage of CORE-Trocar was tested and, there is no air leakage.
The CORE-Trocar therefore meets the performance required by seal test.

- Acceptance Criteria
No air leakage

5) Instrument Comparative test

- Test methods
Put in and draw out the proves below through the each canulla. and check Compatible by O.D size(Maximum and Minimum) with instruments.
In the Instrument compatibility test, all the instruments or bars used were compatible with CORE-Trocar and There’s no crash, no damage, no strong friction. Therefore, CORE-Trocar is acceptable with Instrument compatibility test.

- Acceptance Criteria
no crash, no damage, no strong friction

6) Physical/Chemical

- Test methods

Put in and draw out the proves below through the each canulla. and check Compatible by O.D size(Maximum and Minimum) with instruments. There

Extractable Substance Test is tested accordance with USP 38 <661>.
Nonvolatile Residue, Residue on Ignition, Heavy Metals, Buffering Capacity are acceptable level.

- Nonvolatile Residue

- Test methods

50.0 mL of the test article extract into a white gold plate were evaporated on water bath. After evaporation and transfer Dry Oven on 1 hour at 105 ℃. Measure the weight of a plate and calculate the difference between evaporation before and after.
The test result is 0.11mg, which is acceptable.

- Acceptance Criteria

Residue gap, below 15mg

- Residue on Ignition

- Test methods

Proceeded with the Nonvolatile Residue obtained from the test article extract and from the Blank, using, if necessary, additional sulfuric acid but adding the same amount of sulfuric acid to each crucible, Calculated the difference between the amount of residue on ignition obtained from the test article extract and the blank did not exceed 5 mg.
The test result is not applicable.

- Acceptance Criteria

Residue gap, below 5 mg

- Buffering Capacity

- Test methods

Titrated the previously collected 20mL portion of the test article extract potentiometrically to

a PH of 7.0, using either 0.010N hydrochloric acid or 0.010N sodium hydroxide, as required. Treated a 20mL portion of the blank similarly: if the same titrant was required for both test article extract and blank, the difference between the two volumes is not greater than 10.0mL: and if acid was required for either the test article extract: or the blank and alkali for the other, the total of the two volumes required is not greater than 10.0mL.
The test result is 0.02mL, which is acceptable.

- Acceptance Criteria
Not be darker

■ Heavy Metals
- Test methods
Each 20mL of the test article extract and blank into nessler tube, put 2mL of Pb standard solution in the blank. Adjusted with 1N acetic acid or 6N ammonium hydroxide to a PH between 3.0 and 4.0, using shory-range PH paper as an external indicator, diluted with water to about 35mL, and mixed. After add Thioacetamide-glycerin base TS 1.2mL and PH 3.5 Acetate Buffer 2mL, dilute with water to 50mL, and mix. Compare with the color of the blank and test article extract in white surface(1mg/L(ppm) in extract).
As a result, it was not be darker.

- Acceptance Criteria
Titrant gap (or sum), below 10mL

(3) Performance test – Comparative

Test	Subject device	Criteria	Standard	Result
Seal Test	CORE-Trocar (IC-TC05, IC-TC12) VS Unimicro Trocar System (BTRDSB0510, BTRDSB1210)	The pressure should be maintained at 12~15mmHg.	Internal standard	Pass
Instrument compatibility test		No crash, damage, strong friction	Internal standard	Pass
Obturator compatibility		It should be mated properly without friction, crash, damage. Mating force≤26.7N	Internal standard	Pass
Insertion & Cannula stability		Insertion≤67.8N Removal≤26.7N Fixing≥26.7N	Internal standard	Pass

Air leakage	CORE-Trocar (IC-TC12) VS Unimicro Trocar System (BTRDSB1210)	The pressure should be maintained at 12~15mmHg.	Internal standard	Pass

1) Seal Test

- Test methods

Connect a tube at the check valve of the cannula. Connect a pressure tester and a pressure measuring instrument to the 2-way valve after connecting a 2-way valve to the end of the tube set the pressure tester at a pressure of 15mmHg. Test initially with the trocar ports empty, and then with 2 different diameters metal probes traversing the seal to simulate small and large laparoscopic instrument insertion. repeat traversing 20 times and check the leakage.

- Acceptance Criteria

The pressure should be maintained at 12~15mmHg.

2) Instrument compatibility test

- Test methods

Put in and draw out the proves(Instrument) through the cannula. Repeat putting in and drawing out at least 5 times. check compatibility by O.D size(Maximum and Minimum) with instruments. The size of the probe(Instrument) is chosen as the largest and smallest model that can be inserted into each cannula.

- Acceptance Criteria

No crash, damage, strong friction

3) Obturator compatibility

- Test methods

When mating the obturator with the cannula, the obturator and cannula should be mated properly without friction, crash, damage. And the mating force must not exceed 26.7N

- Acceptance Criteria

It should be mated properly without friction, crash, damage. Mating force≤26.7N

4) Insertion & Cannula stability

- Test methods

We selected pig skin as a sample. And like the surgical conditions, a 0.5~1.5cm incision is made depending on the size of the trocar. When conducting the insertion of Trocar (Obturator + Cannula), removal of Obturator, and fixing of Cannula in conditions similar to the human abdominal cavity, the force must satisfy the acceptance criteria.

- Acceptance Criteria

Insertion≤67.8N, Removal≤26.7N, Fixing≥26.7N

- Typical Condition of abdominal tissue

Under the room temperature of 20 ~ 24℃, pig abdominal skin stored in the oven at 38°C is subjected to the test as soon as it is taken out of the oven.

5) Air leakage

- Test methods

In conditions similar to the human abdominal cavity, insert the cannula. And then Connect a tube at the check valve of the cannula. Connect a pressure tester and a pressure measuring instrument to the 2-way valve after connecting a 2-way valve to the end of the tube set the pressure tester at a pressure of 15mmHg. Test initially with the trocar ports empty, and then with 2 different diameters metal probes traversing the seal to simulate small and large laparoscopic instrument insertion. repeat traversing 20 times and check the leakage value.

- Acceptance Criteria

The pressure should be maintained at 12~15mmHg.

- Typical Condition of abdominal tissue

Under the room temperature of 20 ~ 24℃, pig abdominal skin stored in the oven at 38°C is subjected to the test as soon as it is taken out of the oven.

(4) Shelf Life Test

- Test methods

The CORE-Trocar 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 satety test(Biocompatibility Test, Sterility Test) of the CORE-Trocar is passed. substantially equivalent to the cited predicate device. Performance(Bench, Comparative) of the CORE-Trocar met all acceptance criteria to confirm effectiveness. Through analyzing of comparative test data, we confirmed the subject device CORE-Trocar is substantially equivalent to the predicated device with respect to safety and effectiveness.