9/28/2022

Incore Co., Ltd.
Lee Jae-Hun
Department Head of Regulatory Affairs
11, Hyeoksin-daero, 78-gil, Dong-gu
Daegu, 41072
Korea, South

Re: K220081
Trade/Device Name: CORE-SPORT
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 22, 2022
Received: August 24, 2022

Dear Lee Jae-Hun:

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 Colin Chen
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)*
K220081

Device Name
CORE-SPORT

Indications for Use *(Describe)*
The CORE-SPORT is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.

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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K220081 - 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-SPORT.

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 : Dec 09, 2021

Ⅱ. Device

Trade of Device : CORE-SPORT (K220081)
Model : IC-SP01, IC-SP02, IC-SP03, IC-SP04, IC-SP05
Common or Usual Name : Endoscopy Surgery Instrument
Classification Name : Laparoscope, General & Plastic Surgery
Device Product Code : GCJ
Review Panel : General & Plastic Surgery
Regulation Number : 21 CFR 876.1500 Endoscope and Accessories
Regulatory Class : Class II

Ⅲ. Predicate Device

Trade of Device : GLOVE PORT (K141715)
Common or Usual Name : Endoscopy Surgery Instrument
Classification Name : Laparoscope, General & Plastic Surgery
Device Product Code : GCJ
Review Panel : General & Plastic Surgery
Regulation Number : 21 CFR 876.1500 Endoscope and Accessories
Regulatory Class : Class II

Ⅳ. Device Description

The CORE-SPORT, an surgical instrument that provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery, and consists of a Port-Assay and a Retractor.
Port-Assay consists of several ports of various sizes. Port-Assay consists of 3 or 4 ports and 5 and/or 12 mm sized ports.
The proposed product is packed in Tray & Tyvek following EO Sterilization (SAL 10^{-6}). The device is supplied sterile for single-use and shall be not reused or re-sterilized.

Ⅴ. Indications for Use

The CORE-SPORT is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.

Ⅵ. Comparison of Technological Characteristics with predicate device

There is no technical difference between the CORE-SPORT and the Glove Port. 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-SPORT* Port-Assay A + Retractor	Predicate Device *Glove Port*	Substantial Equivalence
Common or Usual Name	Endoscopy Surgery Instrument	Endoscopy Surgery Instrument	Same
Classfication regulation	21 CFR 876.1500	21 CFR 876.1500	Same
Classification and Code	Class Ⅱ, GCJ	Class Ⅱ, GCJ	Same
Device Classfication Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery	Similar
510(K) number	K220081	K141715	-
Indications for Use	The CORE-SPORT is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.	The Glove Port is intended to provide access for multiple instruments and/or endoscope to the abdominal cavity through a single incision during minimally invasive laparoscopic surgery.	Same
Configuration			Similar

Assembly	Combine Port Base with it, after putting the Retractor on the Bottom part.	No need to assemble (In advance assembled)	Similar
Disposable	Yes	Yes	Same
Material	Polyurethane	Polyurethane	Same
Number of Ports	3 or 4 ea	3~4 ea	Same
Port Size	5 and/or 12 mm	5, 12, and/or 15 mm	Similar
Ring Diameter	86mm	60 ~ 95mm	Similar
Sterilization	EO Gas Sterilization	EO Gas Sterilization	Same

Ⅶ. Performance Data

(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-SPORT 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, Animal intracutaneous reactivity, Guinea pig maximization, Acute systemic toxicity, Pyrogen.

(2) Performance Test – Bench

1) Tensile strength Test

This product is tested for tensile strength in two parts. One is the sheath part, and the other is the ring body and remover part.

First for the sheath part test, fix the retractor ring to one jig of the tensioner and the ring body to the other jig. The product is tensioned at a speed of 150mm/Sec. Second, the test on the ring body and the remover part is conducted under the same test conditions as the first test. Under the conditions of the above method, Test whether the sheath is ruptured by pulling it with a force of 10N.

The tensile strength test of CORE-SPORT was tested, and in both tests, no defects were found after loading 10N. Therefore the CORE-SPORT meets the performance required by tensile strength test.

2) Air leak test

To measure the air tightness of the product, an air leak test was performed. After

connecting the retractor and port-assay with a connector, block the retractor and open one stopcock to inject air at a pressure of 25mmHg.

Under the conditions of the above method, the pressure is maintained over 15mmHg for 30 seconds.

The Air leak test of CORE-SPORT was conducted, and All test results met the criteria.

Therefore the CORE-SPORT meets the performance required by Air leak test of CORE-SPORT test.

3) Physical/Chemical

Extraction Test is tested accordance with USP 38 <661>.

Nonvolatile Residue, Residue on Ignition, Heavy Metal, Buffering Capacity are acceptable level.

(3) Performance Test – Comparative

1) Cavity access test

The cavity access test is a test to prove accessibility for inserting a port during surgery. Check whether the port is of an appropriate size to be inserted into the incision site. When flattening 1/3 of the ring body of the retractor, measure the length of the widest width. As the test result does not exceed the setting criteria(30mm), it is verified that the size is appropriate for cavity access.

2) Maintenance of pneumoperitoneum

the test conducted to confirm that there is no air leakage and pneumoperitoneum is maintained during the operation. The test recognition criteria have to maintain 12-15 mmgH for 30 seconds under the given pressure, and the test results are determined to satisfy this standard.

3) Ability to manipulate instruments

Ability to manipulate instruments is planned to demonstrate that the laparoscopic surgical instruments is applied properly without friction, crash, damage during laparoscopic surgery. If even one friction, crash, damage occurs in the data, it is determined as insufficient.

As a result of the test, it was confirmed that the set criteria were satisfied in the worst case of applying a maximum of 4 surgical instruments.

(4) Shelf Life Test

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