February 23, 2022

Core Access Surgical Technologies, Inc.
Marianne D. Jacklyn
Director of Regulatory Affairs
3495 Piedmont Road, NE Building 11, Suite 905
Atlanta, GA 30305

Re: K212786
Trade/Device Name: LevaLap Laparoscopic Access Device
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF
Dated: January 5, 2022
Received: January 10, 2022

Dear Marianne D. Jacklyn:

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,

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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)*
K212786

Device Name
LevaLap Laparoscopic Access Device

Indications for Use *(Describe)*
The LevaLap Laparoscopic Access Device is intended for use in the peri-umbilical region of the abdominal wall prior to the establishment of a pneumoperitoneum to aid in the insertion of a Veress needle during gynecologic (pelvic) and general surgical (intra-abdominal) laparoscopic 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.

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

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

1 General Information

Submitter Core Access Surgical Technologies, Inc.
3495 Piedmont Road, Building 11, Suite 905
Atlanta, GA 30305 USA

Contact Person Marianne D. Jacklyn, Director of Regulatory Affairs
mjacklyn@castlap.com
+1 (503) 729-9633

2 Date prepared

February 17, 2022

3 Device Information

Trade Name LevaLap Laparoscopic Access Device

Common Name Laparoscopic insufflator

Classification Number 21 CFR 884.1730

Classification Name Laparoscopic insufflator

Product Code HIF

Product Code Name Insufflator, Laparoscopic

Regulatory Class II

4 Predicate Device

Predicate Device Aragon Surgical LapCap (K073452)

The predicate device has not been subject to a design related recall.

5 Device Description

The LevaLap Laparoscopic Access Device is a sterile single-use device, consisting of a clear hemisphere-shaped housing containing a port for connection to a standard operating room (OR) vacuum system and a septum for introduction of a Veress needle. The LevaLap Laparoscopic Access Device is intended to raise the abdominal wall above critical organs and vessels by means of negative pressure, thus creating an initial space prior to insufflation in preparation for laparoscopic access.

6 Indications for Use

The LevaLap Laparoscopic Access Device is intended for use in the peri-umbilical region of the abdominal wall prior to the establishment of a pneumoperitoneum to aid in the insertion of a Veress needle during gynecologic (pelvic) and general surgical (intra-abdominal) laparoscopic procedures.

7 Comparison of Technological Characteristics

The subject and predicate devices have the same intended use and principle of operation, using mechanical force applied via negative pressure to lift the abdominal wall. Both devices consist of a round-shaped housing with an entry point for a Veress needle, and a vacuum intake port to connect to standard vacuum systems. Technological differences are limited to different materials of construction, septum/disc compression design, and the vacuum bypass plug component of the subject device. These differences do not raise different questions of safety and effectiveness.

The subject device has established performance specifications to support its intended use, with testing to demonstrate that these specifications are met. In addition, the finished subject device underwent biocompatibility testing for cytotoxicity, sensitization and irritation, in accordance with ISO 10993-1 and the FDA Guidance on use of this standard.

The subject device includes a vacuum bypass plug positioned in the vacuum intake port. This component is designed to prevent abdominal tissue prolapsing into the vacuum intake port.

In addition to the simulated use testing described below, validation activities for the subject device also included sterilization, packaging integrity and shelf-life testing.

Please refer to Table 1 below for a detailed technological comparison.

Table 1. Device Comparison

Description	**Subject Device**	**Predicate Device (K073452)**
Indications for use	The LevaLap Laparoscopic Access Device is intended for use in the peri-umbilical region of the abdominal wall prior to the establishment of a pneumoperitoneum to aid in the insertion of a Veress needle during gynecologic (pelvic) and general surgical (intra-abdominal) laparoscopic procedures.	The Aragon Surgical LapCap is intended for use in the peri-umbilical region of the abdominal wall with a Veress needle for the establishment of a pneumoperitoneum during gynecologic (pelvic) and general surgical (intraabdominal) laparoscopic procedures.
Description	The LevaLap Laparoscopic Access Device is a sterile single-use device, consisting of a clear hemisphere-shaped housing containing a port for connection to a standard operating room (OR) vacuum system and a septum for introduction of a Veress needle. The device includes a vacuum bypass plug positioned in the vacuum intake port.	The Aragon Surgical LapCap is a single-use device used during laparoscopic surgical procedures. The device consists of a bell-shaped polycarbonate dome housing containing a pass-through port for introduction of a standard Veress needle and a vacuum port for attachment to a standard hospital vacuum line.

Table 1. Device Comparison		
Description	**Subject Device**	**Predicate Device (K073452)**
Principle of operation	Mechanical force is applied by applying vacuum and introducing a negative pressure onto the surface of patient's abdomen, to lift the abdominal wall.	Mechanical force is applied by applying vacuum and introducing a negative pressure onto the surface of patient's abdomen, to lift the abdominal wall.
Materials	Styrene-butadiene copolymers (SBC) Thermoplastic elastomer (TPE)	Polycarbonate No other materials are known
Performance Specifications	Under simulated use conditions, the device maintains consistent negative pressure at -0.8 Bar for a minimum of 1 minute, with a 14G needle inserted in the septum.	Unknown
Testing	The subject device underwent representative functional testing against specified requirements for vacuum draw and vacuum hold at T=0 and after accelerated aging simulating 2 years. In addition, validation activities included sterilization, package integrity, shelf life and biocompatibility testing.	Unknown

8 Non-Clinical Performance

Non-clinical testing was conducted to verify that the LevaLap Laparoscopic Access Device performs as intended. The following non-clinical bench tests were performed successfully on the LevaLap Laparoscopic Access Device: vacuum draw and vacuum hold; biocompatibility according to ISO 10993-1 and the related FDA Guidance; shelf-life testing for package integrity, vacuum draw, and vacuum hold.

9 Conclusion

The subject and predicate devices have the same intended use and similar technological characteristics. The differences in technological characteristics do not raise different questions of safety or effectiveness. Performance testing conducted on the subject device demonstrate that it is as safe and effective as the predicate device to support substantial equivalence.