December 3, 2021

LivsMed Inc.
Dong Wook Lee
Quality Management Representative
#304, D-dong, 700, Pangyo-ro, Bundang-gu, 13516
Seongnam-si, Gyeonggi-do
Republic of Korea

Re: K212500
Trade/Device Name: ArtiSential Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 18, 2021
Received: October 19, 2021

Dear Dong Wook 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 and Part 809); 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,

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)*
K212500

Device Name
ArtiSential Trocar

Indications for Use *(Describe)*
ArtiSential Trocar has an application in general, abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments.

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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K212500

510(k) Summary

1. General Information

Applicant/Submitter: LivsMed Inc.

Address: #304, D-dong, 700, Pangyo-ro, Bundang-gu, 13516
Seongnam-si, Gyeonggi-do, Republic of Korea
Tel) +82-70-4282-7652
Fax) +82-31-706-3211

Contact Person: Dong Wook Lee / QMR
(Quality Management Representative)

Address: #304, D-dong, 700, Pangyo-ro, Bundang-gu, 13516
Seongnam-si, Gyeonggi-do, Republic of Korea
Tel) +82-70-7709-4993
Fax) +82-31-706-3211
Email) dongwook.livsmed@gmail.com

Preparation Date: 11-19-2021

2. Device Name and Code

Device Trade Name	ArtiSential Trocar
Common Name	Sterile Trocars for Endoscopic surgery
Classification Name	Endoscope and accessories
Product Code	GCJ
Regulation Number	21 CFR 876.1500
Classification	Class II
Review Panel	General & Plastic Surgery

3. Predicate Devices

ArtiSential Trocar is the same or similar to the device in Table 3.1.

3.1 Subject Device Description

ArtiSential Trocar is for use during endoscopic minimally invasive procedures or to gain access potential spaces for endoscopic instruments. This device is a sterile, single-use instruments consisting of a main body, cannula, obturator. An optical element, which when used with an endoscope, provides visibility of individual tissue layers during insertion. And a funnel serves as an instrument insertion guide and aids in the insertion of a passive multi-joint surgical instrument into the cannula.

The device falls within Section 876.1500 Endoscope and accessories and is a prescription use only.

Table 3.1 Predicate device

Applicant	Device Name	510(k) Number
Applied Medical Resources Corp.	Modular Trocar System	K060096

4. Indications for Use

4.1 Indications for use

ArtiSential Trocar has an application in general, abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments.

5. Technical Characteristics in Comparison to Predicate Devices

Table 5.1 Comparison of Proposed device and predicate device

	Proposed device	**Predicate device**	**Substantial Equivalence Assessment**
510(K) Number	K212500	K060096	N/A
Manufacture	LivsMed, Inc.	Applied Medical Resources Corp.	N/A
Device Name	ArtiSential Trocar	Modular Trocar System	N/A
Clearance Date	N/A	01-24-2006	N/A
Classification / Regulation	Class 2 / 876.1500	Class 2 / 876.1500	Same
Product Code	GCJ	GCJ	Same
Intended for	Prescription Use	Prescription Use	Same
Indications for Use	ArtiSential Trocar has an application in general, abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments.	The Applied Medical Modular Trocar System is a sterile single use device, or may be used with a reusable stainless steel or reusable DuraGold® cannula and is intended for use in conjunction with Applied's currently marketed trocar products to establish a path of entry for endoscopic instruments for use during general, abdominal, gynecological and	Same

		thoracic minimally invasive procedures or to gain access through tissue planes and/or potential spaces for endoscopic instruments. If utilizing the Applied Medical Optical Separator Obturator with the Modular Trocar System it may be used with or without visualization for primary and secondary insertions.	
Description	ArtiSential Trocar is for use during endoscopic minimally invasive procedures or to gain access potential spaces for endoscopic instruments. This device is a sterile, single-use instruments consisting of a main body, cannula, obturator. An optical element, which when used with an endoscope, provides visibility of individual tissue layers during insertion. And a funnel serves as an instrument insertion guide and aids in the insertion of a passive multi-joint surgical instrument into the cannula.	The Modular Trocar System is a sterile single use device, intended for use in conjunction with Applied's currently marketed Trocar products. A standard trocar assembly consists of an obturator, a seal and a cannula system. The Modular Trocar System will be available in sizes of 5mm, 8mm, 11mm, 12mm and 15mm diameter in lengths ranging from 55mm to 150mm.	Similar: The description of the proposed ArtiSential Trocar is as same as the predicate devices except for the function of the funnel part, which is an optional feature that the user selects. Also, given the technological characteristics of the proposed ArtiSential Trocar are identical to the predicate products. Design verification and validation testing of the proposed Trocar have provided reasonable assurance that the proposed ArtiSential Trocar are appropriate for the proposed indications for use and can be as safely and effectively used

			as predicate devices.
Principles of operation	This product is a sterile, single-use product which is composed of main body, cannula, obturator that is generally used in invasive surgery to create passageways for surgery in the abdomen, gynecology, chest, access through tissues, or to make space for endoscopic instruments. The obturator has an optical element applied to visualize the tissue layer during insertion into the body, and a funnel serves as an instrument insertion guide and aids in the insertion of a passive multi-joint surgical instrument into the cannula.	This product consists of a sleeve and an obturator that are generally used in minimally invasive surgery to create a passageway for surgery in the abdomen, gynecology, chest, access through tissue, or to make space for endoscopic instruments. It is a sterile disposable product. The optical type uses a separate obturator with optical elements applied to visualize the tissue layer during insertion, and the shielded bladed type includes a blade.	Similar: The operation principle of the proposed ArtiSential Trocar is as same as the predicate devices except for the function of the funnel part, which is an optional feature that the user selects. Also, given the technological characteristics of the proposed ArtiSential Trocar are identical to the predicate products. Design verification and validation testing of the proposed Trocar have provided reasonable assurance that the proposed ArtiSential Trocar are appropriate for the proposed indications for use and can be as safely and effectively used as predicate devices.
Physical dimensions and design (diameter, length of Cannula)	-Diameter: 8mm -Length: 100mm	-Diameter: 8mm -Length: 100mm	Same

Raw Materials	-Cannula: Polycarbonate (PC) -Obturator: Polycarbonate (PC)	-Cannula: Copolyester -Obturator: Polycarbonate (PC)	Similar : Raw materials of the proposed ArtiSential Trocar are same as the predicate device(K060096), except Copolyester of the predicate device's raw material. All patient contacting materials of proposed ArtiSential Trocar have been tested per the same standards of ISO 10993-1. Given the favorable biocompatibility test results, the difference between raw material of proposed device and predicate device does not raise different questions in safety and effectiveness.
Sterilization	EO Sterilization	Radiation	Although it is different from the sterilization method of the predicate device, the effectiveness of our sterilization method was verified through the sterilization validation test and the accelerated aging test.

6. Performance Data

6.1 Biocompatibility

The device has been evaluated for its biological safety according to ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process". Following endpoints have been assessed during the evaluation:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Acute systemic toxicity
- Pyrogenicity

6.2 Sterilization

ArtiSential Trocar is provided sterile, intended to be single-use. This product is EO-Sterilization in accordance with ISO-11135.

6.3 Shelf life

The proposed expiration date is 3 years from the manufacturing date.
Following tests were conducted zero time point and 3 years accelerated aging point and the device had passed all tests as below.

1) Packaging and sterility test
   - Packaging integrity test
   - Sealing strength test of packaging (per ASTM F 88/F88M-15)
   - Dye penetration test (per ASTM F1929)
   - Sterility test (per ISO 11737- 2)

2) Performance test
   - Appearance
   - Dimension
   - Leak test
   - Tensile Strength

6.4 Performance test

6.4.1 Bench test

The testing was conducted side-by-side with the predicate device as following and had passed all performed tests.

- Appearance
- Dimension
- Leak test
- Tensile Strength
- the ability to 1) maintain pneumoperitoneum (with and without instruments inserted) and 2) manipulate instruments for laparoscopic surgery.

6.4.2 Animal testing

The device was conducted side-by-side in vivo (micro pig, M-type) testing with the predicate device as following. The device had passed all performed tests.

- Tissue insertion and retention forces
- Intra-abdominal pressure
- Obturator integrity after insertion

Based on these performance characteristics, the results demonstrate that the performance requirements were met, the device performs as intended and that the subject device has the same or similar performance characteristics to the predicate device.

7. Conclusions

Overall, the comparison carried out covers physical dimension, design, performance and the entire indication for use of the device under evaluation. The subject device which is the ArtiSential Trocar is considerably as same as the predicate device in principles of operation, technological characteristics, as well as performance characteristics. The testing was conducted to evaluate the performance of subject device in comparison to the predicate device. Results of validation and verification activities in design control that include testing/certification to designated standards and performance testing of the devices has demonstrated that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device for the requested intended use.
In conclusion, no different questions in safety and effectiveness assessment are being raised compared to the predicate device.