February 13, 2020

Livsmed Inc.
% Do Hyun Kim
CEO
BT Solutions, Inc.
Unit 904, Eonju-ro 86-gil 5, Gangnam-gu
Seoul, Korea 06210

Re: K190909
Trade/Device Name: ArtiSential Bipolar Fenestrated Forceps (Model ABF01-L, ABF01-F)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 21, 2020
Received: January 22, 2020

Dear Do Hyun Kim:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190909

Device Name
ArtiSential Bipolar Fenestrated Forceps (Model name: ABF01-L, ABF01-F)

Indications for Use *(Describe)*
Indications for Use include electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical 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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6. 510(k) Summary

1. General Information

Applicant/Submitter:	Livsmed Inc.
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Contact Person:	Do Hyun Kim, BT Solutions, Inc.
Address:	Unit 904, Eonju-ro 86-gil 5, Gangnam-gu, 06210 Seoul, Republic of Korea Tel) +82-2-538-9140 Fax) +82-2-539-9140 Email) smanager@btsolutions.co.kr
Preparation Date:	01-02-2020

2. Device Name and Code

Device Trade Name:	ArtiSential Bipolar Fenestrated Forceps (Model name: ABF01-L, ABF01-F)
Common Name:	Electrosurgical Instruments
Classification Name:	Electrosurgical, cutting & coagulation & accessories
Product Code:	GEI
Regulation Number:	21 CFR 878.4400
Classification:	Class II
Review Panel:	General & Plastic Surgery

3. Predicate Devices

ArtiSential Bipolar Fenestrated Forceps is substantially equivalent to the following devices

Table 3.1 Predicate device

Applicant	Device Name	510(k) Number

Gyrus Medical, Inc.	Everest Bipolar MACRO, MICRO&MOLLY Forceps Gyrus Bipolar MACRO, MICRO&MOLLY Forceps	K031078

Table 3.2 Reference Predicate device

Applicant	Device Name	510(k) Number
Ethicon Endo-Surgery, LLC	ENSEAL® G2 Articulating Tissue Sealers	K122797
Intuitive Surgical, Inc.	Intuitive Surgical Da Vinci Surgical	K050369
Intuitive Surgical, Inc.	*da Vinci*® *Sp*™ Surgical System, Model SP999, *EndoWrist*® *Sp*™ Instruments, and Accessories	K131962*

* This reference device is referred, of which articulating parts are the same to those of the ArtiSential Bipolar Fenestrated Forceps. This device is used in robotic surgery, but articulating function is very similar.

4. Device Description

This product is sterile, single-use, invasive instrument that used in laparoscopic surgery. There are two models, one for ABF01-F and the other for lock functions, ABF01-L. The two models are same except for lock function. This product is a specific component, but not the entire electrosurgical device. The device is not intended to be marketed with multiple components, accessories, and as part of a system.

5. Indications / Intended Use

5.1 Intended use
The ArtiSential Bipolar Fenestrated Forceps are invasive instruments which is used with electrosurgical generator. They are intended to be used during laparoscopic surgical procedures for incision/coagulation (to electrocauterize, grasp and dissect tissue) during surgery.

5.2 Indications for use
Indications for use include electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.

6. Technical Characteristics in Comparison to Predicate and Reference Devices

ArtiSential Bipolar Fenestrated Forceps is substantially equivalent to the following legally marketed predicate device.

Table 6.1 Predicate Device

ArtiSential Bipolar Fenestrated Forceps

510(k) Summary

	Proposed Device	Predicate Device
510(K) Number	Not Available	K031078
Manufacturer	LivsMed, Inc.	Gyrus Medical, Inc.
Device Name	ArtiSential Bipolar Fenestrated Forceps	Everest Bipolar MACRO, MICRO&MOLLY Forceps Gyrus Bipolar MACRO, MICRO&MOLLY Forceps
Clearance Date:	N/A	05/16/2003
Classification / Regulation	Class 2 / 878.4400	Class 2 / 878.4400
Product Code	GEI	GEI
Intended for	Prescription Use	Prescription Use
Indications for Use	Electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.	Electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.
Principles of operation	This product is a single-use instrument used in electrosurgical units to hold soft tissues or coagulate and make an incision (tissue dissection) during general laparoscopic surgery, which uses the principle of applying high-frequency currents from the electrode to the human body to generate heat by bioimpedance when radio frequency (RF) energy from the electrosurgical unit applies an electric current to the electrode part, and using the generated heat to incise cellular tissues and cause coagulation. It is composed of a jaw, Φ8 diameter shaft, grip (including a control ring), and electrosurgical unit connection electrode connector. During a procedure with this product, the jaw opens if the control ring opens, and jaw closes if the control ring closes. In addition, the jaw is also bent up, down, left and right within a range of ±80° or more by moving the grip up, down, left and right, and the jaw can also turn 360° when rotating the grip.	Unknown
Energy Type	Radiofrequency	Radiofrequency
Electrode type (monopolar or bipolar)	Bipolar	Bipolar
Physical dimensions and design (size, length, connector type)	Shaft diameter: 8mm Length: 411.4mm Connector type: Dual-pin connector type	Shaft diameter: 5mm Length: 450mm Connector type: Dual-pin connector type
Rated voltage	200 Vp	Unknown
Materials (electrode)	Stainless steel	Unknown

Materials (insulation)	Polyetherimide	Unknown
Materials (Shaft)	Glass fiber	Unknown
Rotation	Pitch:±80° or more, Yaw:±80° or more and Open-Close	Unknown
Sterilization	EO	EO

Table 6.2 Reference Predicate Device

	Proposed Device	**Reference Predicate Device 1**	**Reference Predicate Device 2**
510(K) Number	Not Available	K122797	K050369
Manufacturer	LivsMed, Inc.	Ethicon Endo-Surgery, LLC	Intuitive Surgical, Inc.
Device Name	ArtiSential Bipolar Fenestrated Forceps	ENSEAL® G2 Articulating Tissue Sealers	Intuitive Surgical Da Vinci Surgical System, Model IS2000
Clearance Date:	N/A	01/25/2013	04/29/2005
Classification / Regulation	Class 2 / 878.4400	Class 2 / 878.4400 Class 2/ 884.4120	Class 2/ 876.1500
Product Code	GEI	GEI, HGI	NAY
Intended for	Prescription Use	Prescription Use	Prescription Use
Indications for Use	Electrosurgical coagulation, dissection, and grasping of tissue during the performance of laparoscopic and general surgical procedures.	The ENSEAL® G2 Articulating Tissue Sealers are indicated for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures. The devices are bipolar electrosurgical instruments for use with the Generator GEN11 (GEN11). They are intended for use during open or laparoscopic, general and gynecological surgery to cut and seal vessels, and to cut, grasp and dissect tissue during surgery. Indications for use include open and laparoscopic, general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen	The Intuitive Surgical'" da Vinci Surgical System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave ablation probes and accessories during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general non-cardiovascular thoracoscopic

		fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping, and dissection is performed. The devices can be used on vessels up to (and including) 7mm and tissue and/or vascular bundles as large as will fit in the jaws of the instruments.	surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system can also be employed, with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. It is intended for use by trained physicians in an operating room environment in accordance with the representative specific procedures set forth in the Professional Instructions for Use.
Principles of operation	This product is a single-use instrument used in electrosurgical units to hold soft tissues or coagulate and make an incision (tissue dissection) during general laparoscopic surgery, which uses the principle of applying high-frequency currents from the electrode to the human body to generate heat by bioimpedance when radio frequency (RF) energy from the electrosurgical unit applies an electric current to the electrode part, and using the generated heat to incise cellular tissues and cause coagulation. It is composed of a jaw, Φ8 diameter shaft, grip (including a control ring), and electrosurgical unit connection electrode connector. During a procedure with this product, the jaw opens if the control ring opens, and jaw closes if the control ring closes. In addition, the jaw is also bent up, down, left and right within a range of ±80° or more by moving the grip up, down, left and right, and the jaw can also	The ENSEAL G2 Articulating Tissue Sealers have a 5 mm diameter shaft and are available in two shafts lengths: 35 and 45cm; and two jaw types: 3mm curved jaw and 5mm straight jaw. The jaws are normally in the opened position and can be partially or fully closed by squeezing the closing handle. The jaws have atraumnatic teeth for grasping and holding targeted tissue when clamped. The handles of the Subject ENSEAL G2 Articulating Tissue Sealers have an ergonomic interface for the user. Like the Predicate, the Subject devices include an integrated energy activation button. The devices use a combination of the application of bipolar electrosurgical energy in conjunction with the I-BLADE knife, to compress, coagulate, and transect tissue.	This product is a reusable foot control electro-surgical electrode equipped with a product mounted on a cleared product like da Vinci S Surgical system or da Vinci Si Surgical System and used by connecting it to an electrosurgical machine with a cable. It consists of a housing, which is attached to the robotic arm of the da vinci system, and shaft which the bipolar energy is transferred and an electrode (tip) that coagulates, removes, dissects, or destroys tissues using the energy. The principles applied to the development of this product are as follows. When high-frequency energy from an electrosurgical machine is energized on the electrodes through cables, housings, and shafts, high-frequency currents from electrodes are applied to the human body to generate heat due to bio-resistance, and the heat generated is used to generate incision and coagulation of tissue. This product is a medical device that can be reused by

	turn 360° when rotating the grip.		cleaning and sterilizing after use.
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency
Electrode type (monopolar or bipolar)	Bipolar	Bipolar	Bipolar
Physical dimensions and design (size, length, connector type)	Shaft diameter: 8mm Length: 411.4mm Connector type: Dual-pin connector type	Shaft diameter: 5mm Length: 350mm, 450mm Connector type: Unknown	Shaft diameter: 8mm Total length: 511mm Connector type: Dual-pin connector type
Rated voltage	200 Vp	Unknown	384 Vp
Materials (electrode)	Stainless steel	Stainless steel	Stainless steel
Materials (insulation)	Polyetherimide	Unknown	Polyetherimide / ETFE (Ethylenetetrafluoroethylene)
Materials (Shaft)	Glass fiber	Unknown	Glass fiber
Rotation	Pitch:±80° or more, Yaw:±80° or more and Open-Close	Articulates approximately 50~65° to the left and the right of center and Open-Close	Pitch:±70° Yaw:±90°
Sterilization	EO	EO	Moist Heat or Steam Sterilization

7. Performance Data

7.1 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

7.2 Electrical Safety

The ArtiSential Bipolar Fenestrated Forceps has been tested according to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-18 and IEC 60601-2-2. The test setup included:

- Active accessory insulation
- Active accessory hf leakage
- Active accessory hf dielectric strength
- Active accessory mains frequency dielectric strength
- Feedthrough test

The device had passed all performed tests.

7.3 Sterilization

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

7.4 Shelf life

The proposed expiration date is 2 years from the manufacturing date. The real-time testing will be performed to confirm the shelf-life for 3 years.

7.5 Performance test

Test clause and Test requirement	Test specification	Results- Remarks
1. Appearance There should be no defects in the appearance of the product and there should be no problem in use.	Visual observation	No crack, stain or no substances on the surface of the product
2. Dimension It should be within ± 5% of the indicated value of the dimensional term.	Measure by Vernier calipers and dial gauge etc.	Pass Refer to [Measurement data] on 65 page at attachment #3
3. Operational test The jaw must be smoothly opened and closed and free from jamming, the jaw and hub can be bent up, down, left, and right a range of above ±80° and are capable of 360° rotation.	Adjusting open and close the jaw by manipulating the grip and control ring, and measure the angle at bending and turning.	The jaw and hub are bent up, down, left and right within above 80°, and can rotate 360°.
4. Tensile strength The jaw and shaft connections shall not be damaged from pulling of 20 N.	Hold the jaw and shaft connections respectively and apply a force of 20 N using Push pull gauge.	No damage to the connection when applying a force of 20N
5. Feedthrough test Electricity should be transmitted between the electrode tip and the connector.	Electrical conduction between the electrode tip and the connector is tested using a DMM (digital multi meter).	The resistance value between the electrode tip and the connector is less than 1Ω

The device had passed all performed tests.

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 substantially equivalent performance characteristics to the predicate and reference predicate devices.

8. Substantial Equivalence

The ArtiSential Bipolar Fenestrated Forceps indication for use is similar to the predicate device (K031078). The energy type, electrode type, sterilization as well as similar physical characteristics are the same. Although there are some minor differences with each product, these differences between the ArtiSential Bipolar Fenestrated Forceps and the predicate device do not raise new or different questions of safety and efficacy. There is no new technology and no difference that would raise new or different questions of safety or efficacy.

9. Conclusions

In conclusion, the comparison carried out covers all products, models, sizes, and the entire intended purpose of the device under evaluation. The subject device which is the Disposable Laparoscopic Instruments – ArtiSential Bipolar Fenestrated Forceps – is considerably similar to the predicate and reference devices 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 and reference devices. Results of validation and verification activities in design control that include testing/certification to designated standards and performance testing of the devices has demonstrated substantial equivalence of the subject device to the predicate in terms of safety and effectiveness for requested intended use.