March 22, 2019

ELMED Incorporated
Werner Hausner
President
35 N Brandon Drive
Glendale Heights, Illinois 60139

Re: K181173
Trade/Device Name: ELMED Laparoscopic Instruments and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, GEI
Dated: February 20, 2019
Received: February 21, 2019

Dear Werner Hausner:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.03.22 10:05:03 -04'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K181173

Device Name
ELMED LAPAROSCOPIC INSTRUMENTS AND ACCESSORIES

Indications for Use *(Describe)*
The ELMED Laparoscopic Instruments are intended for use in a variety of laparoscopic/endoscopic, therapeutic and minimally invasive general surgical procedures for grasping, dissecting, manipulating, retracting, cutting, suturing, occluding or clamping soft tissue.

The Laparoscopic Electrodes are electrosurgical devices intended to be used for a variety of general laparoscopic procedures through a port, for coagulation and transection of soft tissue by use of high frequency electric current.

Manually operated surgical instruments are available with or without monopolar high frequency connection and are designed to be used through an opening maintained by a cannula which allows inserting and removal of the instrument(s) without damaging the tissue(s).

Bipolar Forceps are designed to grasp, manipulate and coagulate selected soft tissue and are intended for use in general surgical procedures. They are connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator.
Suction/ Irrigation Cannulas have an application(s) in laparoscopic procedures such as gynecologic, general, thoracic and urology and are intended to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.
Trocars and Trocar Sleeves are intended to create portals into an operative site for the direct visualization and/or inserting of other surgical instruments.
Needle holders are intended to grasp and manipulate needles inside the peritoneal cavity enabling a surgeon to suture internal soft tissue during a laparoscopic procedure.

Instruments should be used only by personnel completely familiar with their operation.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5: 5l0(k) Summary

These 510(k) summary is being submitted in accordance with 21 CFR §807.92.

Type of submission: Traditional

The assigned 510 (k) number is: K181173

A. Company Contact

ELMEDINCORPORATED
35 N Brandon Drive
Glendale Heights, IL 60139

B. **Submitter** Information:

Werner Hausner
President
ELMEDINCORPORATED
werner@elmed.com

C. **Identification of the Device**:

Proprietary Name: ELMED Laparoscopic Instruments and Accessories
Common Name: Laparoscopic Instrument and Accessory
Classification Name: Laparoscope, General and Plastic surgery
Product Code: GCJ
Secondary Product Code: GEI
Regulatory Class: Class II 21 CFR 876.1500
Panel: General and Plastic Surgery

D. Identification of the Predicate Device

Legally Marketed Equivalent Devices

Table 1: *Predicative Device Information*

Manufacturer	Brand Name	510(k) Number
JAKOUBEK MEDIZINTECHNIK GMBH	TROCAR & TROCAR SLEEVES, LAPAROSCOPES, LAPAROSCOPIC FORCEPS, & LAPAROSCOPIC INSTRUMENTS	K990785
HANS HERMANN GMBH	HANS HERMANN LAPAROSCOPES AND ACCESSORIES	K051610

E. Device Description:

These devices represent a family of Laparoscopic/Endoscopic Instruments and Accessories that consist of:

- Laparoscopic Monopolar electrodes
- Laparoscopic Bipolar forceps
- Laparoscopic Trocars, Trocar sleeves
- Laparoscopic Needle Holders
- Laparoscopic Suction/ Irrigation Cannulas
- Laparoscopic Suture and Ligature Instruments
- Laparoscopic various manually operated surgical instruments with and without monopolar high frequency connection (scissors, graspers/dissectors, biopsy forceps)
- Laparoscopic Accessories such as: Cleaning Brushes, Sealing Caps, Adapters

Various configurations, sizes and handles of the jaws (graspers, forceps, scissors, dissectors, biopsy, and punches) exist to meet the needs of surgical procedures in conjunction with a laparoscope/endoscope. The instruments have the capability for monopolar RF current, if needed. These instruments are composed of biocompatible materials (surgical grade stainless steel, PTFE, PEEK, several coatings, silicon and brass chromium plated). These materials have a long history of biocompatibility for human use at short term contact. The instruments are reusable and sold non-sterile.

F. Intended Use and Indication for Use of the subject device(s):

The ELMED Laparoscopic Instruments are intended for use in a variety of laparoscopic/endoscopic, therapeutic and minimally invasive general surgical procedures for grasping, dissecting, manipulating, retracting, cutting, suturing, occluding or clamping soft tissue.

The Laparoscopic Electrodes are electrosurgical devices intended to be used for a variety of general laparoscopic procedures through a port, for coagulation and transection of soft tissue by use of high frequency electric current.

Manually operated surgical instruments are available with or without monopolar high frequency connection and are designed to be used through an opening maintained by a cannula which allows inserting and removal of the instrument(s) without damaging the tissue(s).

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Trocars and Trocar Sleeves are intended to create portals into an operative site for the direct visualization and/or inserting of other surgical instruments. Needle holders are intended to grasp and manipulate needles inside the peritoneal cavity enabling a surgeon to suture internal soft tissue during a laparoscopic procedure.

Instruments should be used only by personnel completely familiar with their operations.

G. Non-clinical Testing

The devices conform to IEC 60601-2-2 . Testing conducted on the instruments also included but was not limited to:

1. Mechanical Stress Testing
2. Mechanical Push/Pull Testing
3. Drop Testing
4. Dielectric Strenght Testing
5. Capacitive Coupling Testing
6. Leakage Current Testing
7. Electromagnetic Interference/Immunity Testing

The results also demonstrate that ELMED Laparoscopic Instruments and Accessories are as safe and effective as the predicate device.

H. Clinical Testing

There were no prospective clinical studies to support the medical device as the indications for use, technology; materials of construction are virtually identical to the predicate device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

I. Substantial Equivalence/ Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.
The differences between the predicates and the modified design do not raise any new risks of safety or efficacy. The changes are minor, so the subject devices are as safe and effective as the predicate devices, perform similarly to other legally marketed predicate devices for laparoscopic/endoscopic and minimally invasive procedure. ELMED Laparoscopic Instruments and Accessories are as safe and effective as the predicate device.