February 13, 2018

Hunan Handlike Minimally Invasive Surgery Co., Ltd
% Ms. Elly Xu
Shenzhen Joyantech Consulting Co., Ltd
Room 1122, No.55 Shizhou Middle Road, Nanshan District
Shenzhen, Guangdong, P.R.China

Re: K171825
Trade/Device Name: Endoscopic Surgical Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 10, 2017
Received: December 18, 2017

Dear Ms. Xu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Jennifer R. Stevenson -S3

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)*
K171825

Device Name
Endoscopic Surgical Instrument

Indications for Use *(Describe)*
Endoscopic Instruments are designed to cut, dissect, manipulate and/or cauterize various tissues during endoscopic/ laparoscopic, 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

VOL 005_510(k) Summary

This 510(K) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Submission Sponsor

Applicant Name	Hunan Handlike Minimally Invasive Surgery Co.,Ltd
Address	A4, Lugu Yuyuan, #27, Wenxuan Rd, High-tech Zone, Changsha, Hunan, CHINA
Post Code	410205
Phone No.	86-731-89727782
Fax No.	86-731-88830694
Contact Person	Hanhan Hu
Email	huhanhan@handlike.cn
Date Prepared	2018-2-10

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	Room 1122, No.55 Shizhou Middle Road, Nanshan District, Shenzhen, Guangdong, P.R.China
Post Code	518000
Phone No.	86-755-86069197
Contact Person	Elly Xu; Field Fu
Email	elly@cefda.com; cefda13485@163.com

3. Devices Identification

Trade name	Endoscopic Surgical Instrument
Common name	Endoscopic Surgical Instrument
Model	Disposable Endoscopic Surgical Instrument Reusable Endoscopic Surgical Instrument
Classification	II
Classification name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation number	878.4400
Product code	GEI
510(k) review panel	General & Plastic Surgery
Performance standards	The performance and safety was evaluated in

	accordance with Electrosurgical Device Guidance of FDA. Biocompatibility tests were done in conformance with relevant requirements of ISO10993.

4. Legally Marketed Predicate Devices

Trade Name	Endoscopic Surgical Instruments
Regulation number	878.4400
Regulation class	II
Regulation name	Electrosurgical, Cutting & Coagulation & Accessories
510(k) Number	K132771
Product Code	GEI
Manufacturer	Qingdao Kingston Medical Devices Ltd.

Trade Name	Endoscopic Surgical Instruments
Regulation number	878.4400
Regulation class	II
Regulation name	Electrosurgical, Cutting & Coagulation & Accessories
510(k) Number	K102921
Product Code	GEI
Manufacturer	BEMA GmbH & Co. KG

5. Device Description

Endoscopic Surgical Instrument is a kind of device used to cut, dissect, manipulate and/or cauterize various tissues during endoscopic/laparoscopic, general surgical procedures. The device includes Disposable Endoscopic Surgical Instrument and Reusable Endoscopic Surgical Instrument. Both of the disposable and reusable endoscopic instruments are provided sterile when they’re released. After used for the first time, Reusable Endoscopic Instrument needs to be sterilized by the end users. The instruments are 5mm in diameter as well as 340mm in length.

6. Indications for Use Statement

Endoscopic Instruments are designed to cut, dissect, manipulate and/or cauterize various tissues during endoscopic/laparoscopic, general surgical procedures.

7. Substantial Equivalence Discussion

7.1 Comparison between Disposable Endoscopic Surgical Instrument and K132771

Characteristic	Disposable Endoscopic Surgical Instrument	Endoscopic Surgical Instrument	Comments
Indication for	Disposable Endoscopic	The Endoscopic Surgical	Same

use/Intended use	Surgical is designed to cut, dissect, manipulate and/or cauterize various tissues during endoscopic/laparoscopic, general surgical procedures.	Instruments are intended for cutting, grasping,dissecting and coagulation of soft tissue in endoscopic surgical procedures. They are intended for single patient use.	
Operation mode	Devices are either monopolar endoscopic instruments for tissue manipulation and cutting/coagulation, or non-powered endoscopic instruments for tissue manipulation dissection, and cutting.	Devices are either monopolar endoscopic instruments for tissue manipulation and cutting/coagulation, or non-powered endoscopic instruments for tissue manipulation dissection, and cutting.	Same
Structure	Handle, shaft and dissector/grasper/scissor jaw	Handle, shaft and dissector/grasper/scissor jaw	Same
Diameter	5mm/34cm	5mm/33cm (or 42cm)	Similar
Sterilization	EO	EO	Same
Single Use	Yes	Yes	Same
Biocompatibility	Comply with ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-11 ISO 10993-12	Comply with ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-11 ISO 10993-12	Same
Electric Safety, EMC and Performance Test	lEC 60601-1, lEC 60601-1-2 IEC 60601-2-2 IEC 60601-2-18	lEC 60601-1, lEC 60601-1-2 IEC 60601-2-2	Same

7.2 Comparison between Reusable Endoscopic Surgical Instrument and K102921

Characteristic	**Reusable Endoscopic Surgical Instrument**	**Endoscopic Monopolar Instruments and Accessories**	**Comments**
Indication for use/ Intended use	Reusable Endoscopic Surgical is designed to cut, dissect, manipulate and/or	Endoscopic Monopolar Instruments and Accessories are used in	Same

	cauterize various tissues during endoscopic/laparoscopic, general surgical procedures.	laparoscopic and other minimally invasive procedures for cutting, dissection, fixation and taking of biopsy samples, depending on the design of the tip. They are also intended to control bleeding by use of monopolar high-frequency electrical current.	
Operation mode	Devices are either monopolar endoscopic instruments for tissue manipulation and cutting/coagulation, or non-powered endoscopic instruments for tissue manipulation dissection, and cutting.	Devices are either monopolar endoscopic instruments for tissue manipulation and cutting/coagulation, or non-powered endoscopic instruments for tissue manipulation dissection, and cutting.	Same
Structure	Handle, shaft and dissector/grasper/scissor jaw	Handle, shaft and tip	Same
Design	Assembly type, Tip-detachable type	Two and Three-piece modular system, Single-piece instrument	Similar, see Note 1
Diameter	5mm/34cm	Unknown	See Note 2
Sterilization	EO and Steam	Steam	See Note 3
Biocompatibility	Comply with ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-11 ISO 10993-12	Comply with ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-11 ISO 10993-12	Same
Electric Safety, EMC and Performance Test	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 IEC 60601-2-18	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Same

Note 1: The Assembly type and Tip-detachable type is similar with Two-piece modular system. Both the subject device and the predicate device can be detached into two pieces.

Note 2: The diameter of Reusable Endoscopic Surgical Instrument is similar to

Endoscopic Surgical Instrument (K132711).

Note 3: The reusable endoscopic instruments are provided sterile when they're released from the manufacture. After used for the first time, Reusable Endoscopic Instrument needs to be steam sterilized by the end users. Both the EO and the steam sterilization have been validated, and the test reports show that the sterilization effect of the proposed device can achieve a Sterility Assurance Level (SAL) of 10^{-6}.

8. Non-clinical Testing

Evidence of safety and effectiveness was obtained from electrical safety testing and performance testing as following:

Testing in accordance with IEC 60601-1
Testing in accordance with IEC 60601-1-2
Testing in accordance with IEC 60601-2-2
Testing in accordance with IEC 60601-2-18

Moreover, other performance testing of Endoscopic Surgical Instruments were conducted included appearance, basic dimension, corrosion resistance, transverse holding force, longitudinal holding force, ratchet holding force, cutting efficacy and thermal effects on tissue. The thermal effect have been performed on the fresh pig's liver, kidney and muscle tissue. And the thermal damage zone is measured under magnification using histology after performing cauterizing. All the testing results show that the Endoscopic Surgical Instruments meet the specification and performance characteristics as identified in internal design control procedures.

Biocompatibility testing of the Endoscopic Surgical Instrument confirmed that the device meets the applicable requirements of the FDA Blue Book Memorandum G95-1I entitled Use of International Standards ISO 10993-1:2009 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing within a risk management process.

All testings above were conducted per Electrosurgical Device Guidance of FDA.

9. Clinical Testing

Substantial equivalence does not depend on clinical test data.

10. Conclusions

Based on device comparison information and non-clinical testing, the differences between Endoscopic Surgical Instrument and predicate devices will be not raise any new issues of safety and effectiveness, Endoscopic Surgical Instrument is substantially equivalent to legally marketed predicate devices.