September 30, 2022

Miconvey Technologies Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K210567
Trade/Device Name: Ultrasonic Surgical System
Regulatory Class: Unclassified
Product Code: LFL
Dated: August 29, 2022
Received: August 29, 2022

Dear Diana Hong:

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,

Colin K. Chen, Ph.D.
Acting 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)*
K210567

Device Name
K500 Ultrasonic Surgical System

Indications for Use *(Describe)*
The K500 Ultrasonic Surgical System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The scalpel can be used as an adjunct or substitute for electrosurgery, laser and steel scalpels.

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.

K210567 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Preparation: 09/26/2022

2. Sponsor Identification

Miconvey Technologies Co., Ltd.
No.16 Fangzheng Avenue, Beibei District, Chongqing, 400714, China

Establishment Registration Number: Not yet registered

Contact Person: Kang Li
Position: General Manager
Tel: +86-23-63171596
Fax: +86-23-63171516
Email: kang.li@miconvey.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: K500 Ultrasonic Surgical System
Common Name: Ultrasonic Surgical Generator and Accessory
Model: K500

Regulatory Information:
Classification Name: Instrument, Ultrasonic Surgical
Classification: Unclassified; Pre-amendment
Product Code: LFL;
Regulation Number: N.A. Review Panel:
General& Plastic Surgery;

Indication for Use Statement:

The K500 Ultrasonic Surgical System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The scalpel can be used as an adjunct or substitute for electrosurgery, laser and steel scalpels.

Device Description

Ultrasonic Surgical System consists of a generator, a foot switch, a scalpel and a hand piece. In addition, a cart is provided as an optional component. The electrical energy supplied by the generator will be converted into mechanical motion by the transducer in hand piece, which will drive the scalpel vibrate longitudinally. The foot switch is used to control the activation of energy output. The scalpels are used to cut and coagulate soft bodily tissues and structures in many surgery procedures.

5. Identification of Predicate Devices

Primary Predicate Device

510(k) Number: K002906
Product Name: Ultracision Harmonic Scalpel System
Model Name: GEN04
Manufacturer: Ethicon Endo-Surgery, LLC

Secondary Predicate Device

510(k) Number: K042777
Product Name: Harmonic ACE^{TM} Curved Shears with Hand Control

Manufacturer: Ethicon Endo-Surgery, LLC

6. Summary of Technological Characteristics

Table 1 Comparison of Technology Characteristics- Ultrasonic Surgical System

Item	Proposed Device	Primary Predicate Device K002906	Remark
Product Code	LFL	LFL	Same
Classification	Unclassified	Unclassified	Same
Regulation Number	N.A.	N.A.	Same
Intended Use	The K500 Ultrasonic Surgical System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The scalpel can be used as an adjunct or substitute for electrosurgery, laser and steel scalpels.	The Ultracision Harmonic Scalpel System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The Ultracision Harmonic Scalpel System instruments can be used as an adjunct or substitute for electrosurgery, laser and steel scalpels.	Same
Configuration	Generator	Generator	Same
	Footswitch	Foot Switch	Same
	Hand piece	Hand piece	Same
	Scalpel	N.A.	Different
Sterile	Generator- Nonsterile	Generator- Nonsterile	Same
	Handpiece- Nonsterile. Sterilization required prior to use.	Handpiece- Nonsterile. Sterilization required prior to use.	Same
	Scalpel-Provided sterile	N.A.	Different
Biocompatibility	No Patient Contact Material	No Patient Contact Material	Same
Electrical Safety	Comply with AAMI/ANSI/ ES 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

Table 2 Comparison of Technology Characteristics- Ultrasonic Surgical System-Scalpel

Item	Proposed Device	Secondary Predicate Device K042777	Remark
Product Code	LFL	LFL	Same
Classification	Unclassified	Unclassified	Same
Regulation Number	N.A. Pre-Amendment	N.A. Pre-Amendment	Same
Intended Use	The K500 Ultrasonic Surgical System is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The scalpel can be used as an adjunct or substitute for electrosurgery, laser and steel scalpels.	The Harmonic ACE™ Curved Shears with Hand Control is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, pediatric, gynecologic, urologic and other open and endoscopic procedures.	Same
Shaft length	14cm, 23cm and 36cm	23cm and 36cm	Different
Pin hole to proximal end	18.85mm	18.85mm	Same
Pin hole diameter	1.8mm	1.8mm	Same
Tip diameter	2.14mm	2.16mm	Similar
Jaw diameter	5.45mm	5.45mm	Same
Rotary head length	2.9mm	2.9mm	Same
Handle length	36.9mm	37mm	Similar
Handle width	30.05mm	30mm	Similar
Closing trigger width	Upper width: 3.2mm Lower width: 7mm	Upper width: 3.2mm Lower width: 7mm	Same
Trigger button length	2.2mm	2.2mm	Same
Torque wrench diameter	8.15mm	8.15mm	Same
Shaft diameter	3.42mm	3.42mm	Same
Blade shape	Curved	Curved	Same
Energy Type	Ultrasonic and Mechanical	Ultrasonic and Mechanical	Same
Sterility	10^{-6} SAL	10^{-6} SAL	Same
Single Use	Single Use	Single Use	Same
Biocompatibility	Pass	Pass	Same

Electrical Safety	Comply with AAMI/ANSI/ES 60601-1	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

Different-Shaft Length

The proposed scalpel is available in three shaft length 14cm, 23cm and 36cm and two shaft length models are covered in predicate device. The different shaft length does not affect the indication of soft tissue incisions.

Similar-Tip Diameter

The tip diameter for the proposed device is different from predicate device. In addition, this difference is very slight and animal study has been conducted on the subject device and predicate device. The animal study result showed there were no significant difference.

Similar-Handle Length and Handle Width

The handle length and width for the proposed device is different from predicate device. In addition, this difference is very slight and does not affect intended use.

7. Software

Software verification and validation testing were conducted, and documentation was provided in accordance with FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

8. Summary of Non-clinical Performance Testing

Nonclinical performance comparison tests were conducted to verify that the proposed device met all design specifications. The tests performed on the subject device included testing and evaluation for vessel burst pressure, thermal spread, acute animal vessel sealing study, and chronic animal survival study.

The biocompatibility tests were performed on the proposed device. Based on the contact level and contact duration, the proposed device was tested for skin sensitization (ISO 10993-10), intracutaneous reactivity (ISO 10993-10), cytotoxicity (ISO 10993-5), pyrogenicity (ISO 10993-11) and system toxicity (ISO 10993-11).

Electrical safety and EMC test was conducted on the proposed device per AAMI/ANSI ES 60601-1, IEC 60601-2-18 and IEC 60601-1-2.

The following testing demonstrated that the subject device complies with the following standards:

- AAMI/ANSI/ ES 60601-1:2005/(R)2012 and A1: 2012, C1:2009(R)2012 and A2:2010(R)2012(Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- IEC 60601-2-18:2009 Medical electric equipment- Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests;
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity;
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- ASTM F88/F88M-15 Standard method for seal strength of flexible barrier materials
- GB18280:2007 (IDT ISO 11137: 2006)

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion

The conclusions drawn from the subject device indications for use, technological characteristics and performance testing demonstrates that the subject device is as safe and effective as and is substantially equivalent to the legally marketed predicate devices.