October 12, 2023

VHMED (Nantong) Co. Ltd.
% Jun Peng
Principal Consultant
P&L Scientific, Inc.
1430 S. Dixie Hwy Suite 105
Coral Gables, Florida 33146

Re: K230650
Trade/Device Name: Monopolar Electrode 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: September 12, 2023
Received: September 12, 2023

Dear Jun Peng:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Chen -S Digitally signed by Long H. Chen -S
Date: 2023.10.12 13:24:14 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K230650

Device Name
Monopolar Electrode Surgical Instrument

Indications for Use *(Describe)*
The device is a family of instruments which includes scissors, probes and forceps which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar Electrosurgical cutting and/or coagulation.

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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VHMED (Nantong) Co. Ltd.

K230650

510(k) Summary

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

1. Applicant/Submitter

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2. Submission Contact Person

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3. Subject Device

Trade Name: Monopolar Electrode Surgical Instrument

Common Name: Laparoscopic Instrument and Accessory

Classification Name: Electrosurgical, Cutting & Coagulation & Accessories

Classification Regulation Number: 878.4400

Device Class: II

Product Code: GEI

4. Predicate Device

Table 1. Predicative Device Information

Manufacturer	Device Name	510(k) Number
Unimicro Medical Systems(Shenzhen) Co., Ltd.	Monopolar Laparoscopic Accessories	K142208

5. Device Description

The Monopolar Electrode Surgical Instrument is a kind of device used to cut, dissect, manipulate and/or cauterize various tissues during endoscopic/laparoscopic, general surgical procedures. The Monopolar Electrode Surgical Instrument is provided sterile when they're released. The device consists of a conductive jaw tip, an insulated shaft and a conductive post which allows it can be connected through an appropriate cable to an electrosurgical generator. The device is available with different handles and different tip designs.

6. Product Specification

Table A. Models and Specifications for Monopolar Scissors

Device Name: Monopolar Electrode Surgical Instrument Jaw Tip Family: Scissors		
Model	Device Description	Specification
LS1001S	Monopolar Curved Metzenbaum Scissors, insulation to the tip	Φ5*250mm
LS1001	Monopolar Curved Metzenbaum Scissors, insulation to the tip	Φ5*330mm
LS1001L	Monopolar Curved Metzenbaum Scissors, insulation to the tip	Φ5*450mm
LS1002S	Monopolar Curved Metzenbaum Scissors	Φ5*250mm
LS1002	Monopolar Curved Metzenbaum Scissors	Φ5*330mm
LS1002L	Monopolar Curved Metzenbaum Scissors	Φ5*450mm
LS1003S	Monopolar Curved Mini Metzenbaum Scissors, insulation to the tip	Φ5*250mm
LS1003	Monopolar Curved Mini Metzenbaum Scissors, insulation to the tip	Φ5*330mm
LS1003L	Monopolar Curved Mini Metzenbaum Scissors, insulation to the tip	Φ5*450mm
LS1004S	Monopolar Straight Metzenbaum Scissors	Φ5*250mm
LS1004	Monopolar Straight Metzenbaum Scissors	Φ5*330mm
LS1004L	Monopolar Straight Metzenbaum Scissors	Φ5*450mm
LS1041S	Articulating Curved Metzenbaum Scissors	Φ5*250mm
LS1041	Articulating Curved Metzenbaum Scissors	Φ5*330mm
LS1041L	Articulating Curved Metzenbaum Scissors	Φ5*450mm
LS6001S	Monopolar Curved Metzenbaum Scissors, insulation to the tip	Φ3*200mm
LS6001	Monopolar Curved Metzenbaum Scissors, insulation to the tip	Φ3*280mm
LS6001L	Monopolar Curved Metzenbaum Scissors, insulation to the tip	Φ3*340mm

Table B. Models and Specifications for Monopolar Dissecting Forceps

Device Name: Monopolar Electrode Surgical Instrument Jaw Tip Family: Dissecting Forceps

Model	Device Description	Specification
LS1011S	Monopolar Maryland Dissector	Φ5*250mm
LS1011	Monopolar Maryland Dissector	Φ5*330mm
LS1011L	Monopolar Maryland Dissector	Φ5*450mm
LS1012S	Monopolar Modified Maryland Dissector	Φ5*250mm
LS1012	Monopolar Modified Maryland Dissector	Φ5*330mm
LS1012L	Monopolar Modified Maryland Dissector	Φ5*450mm
LS1042S	Articulating Maryland Dissector	Φ5*250mm
LS1042	Articulating Maryland Dissector	Φ5*330mm
LS1042L	Articulating Maryland Dissector	Φ5*450mm
LS6011S	Monopolar Maryland Dissector	Φ3*200mm
LS6011	Monopolar Maryland Dissector	Φ3*280mm
LS6011L	Monopolar Maryland Dissector	Φ3*340mm

Table C. Models and Specifications for Monopolar Grasping Forceps

Device Name: Monopolar Electrode Surgical Instrument Jaw Tip Family: Grasping Forceps		
Model	Device Description	Specification
LS1021S	Monopolar Fenestrated Johann Grasper	Φ5*250mm
LS1021	Monopolar Fenestrated Johann Grasper	Φ5*330mm
LS1021L	Monopolar Fenestrated Johann Grasper	Φ5*450mm
LS1022S	Monopolar Long Jaw Fenestrated Johann Grasper	Φ5*250mm
LS1022	Monopolar Long Jaw Fenestrated Johann Grasper	Φ5*330mm
LS1022L	Monopolar Long Jaw Fenestrated Johann Grasper	Φ5*450mm
LS1023S	Monopolar Extra Long Jaw Fenestrated Johann Grasper	Φ5*250mm
LS1023	Monopolar Extra Long Jaw Fenestrated Johann Grasper	Φ5*330mm
LS1023L	Monopolar Extra Long Jaw Fenestrated Johann Grasper	Φ5*450mm
LS1024S	Monopolar Blunt Tip Atraumatic Grasper	Φ5*250mm
LS1024	Monopolar Blunt Tip Atraumatic Grasper	Φ5*330mm
LS1024L	Monopolar Blunt Tip Atraumatic Grasper	Φ5*450mm
LS1025S	Monopolar Clinch Grasper	Φ5*250mm
LS1025	Monopolar Clinch Grasper	Φ5*330mm
LS1025L	Monopolar Clinch Grasper	Φ5*450mm
LS1026S	Monopolar Rat Tooth Claw Grasper	Φ5*250mm
LS1026	Monopolar Rat Tooth Claw Grasper	Φ5*330mm
LS1026L	Monopolar Rat Tooth Claw Grasper	Φ5*450mm
LS1027S	Monopolar Babcock Grasper	Φ5*250mm
LS1027	Monopolar Babcock Grasper	Φ5*330mm
LS1027L	Monopolar Babcock Grasper	Φ5*450mm
LS1028S	Monopolar Allis Grasper	Φ5*250mm

Device Name: Monopolar Electrode Surgical Instrument Jaw Tip Family: Grasping Forceps		
Model	Device Description	Specification
LS1028	Monopolar Allis Grasper	Φ5*330mm
LS1028L	Monopolar Allis Grasper	Φ5*450mm
LS1029S	Monopolar Duckbill Grasper	Φ5*250mm
LS1029	Monopolar Duckbill Grasper	Φ5*330mm
LS1029L	Monopolar Duckbill Grasper	Φ5*450mm
LS1030S	Monopolar Wave Teeth Grasper	Φ5*250mm
LS1030	Monopolar Wave Teeth Grasper	Φ5*330mm
LS1030L	Monopolar Wave Teeth Grasper	Φ5*450mm
LS1043S	Articulating Monopolar Johann Fenestrated Grasper	Φ5*250mm
LS1043	Articulating Monopolar Johann Fenestrated Grasper	Φ5*330mm
LS1043L	Articulating Monopolar Johann Fenestrated Grasper	Φ5*450mm
LS1044S	Articulating Clinch Grasper	Φ5*250mm
LS1044	Articulating Clinch Grasper	Φ5*330mm
LS1044L	Articulating Clinch Grasper	Φ5*450mm
LS6021S	Monopolar Johann Fenestrated Grasper	Φ3*200mm
LS6021	Monopolar Johann Fenestrated Grasper	Φ3*280mm
LS6021L	Monopolar Johann Fenestrated Grasper	Φ3*340mm
LS6022S	Monopolar Long Jaw Fenestrated Johann Grasper	Φ3*200mm
LS6022	Monopolar Long Jaw Fenestrated Johann Grasper	Φ3*280mm
LS6022L	Monopolar Long Jaw Fenestrated Johann Grasper	Φ3*340mm
LS6023S	Monopolar Extra Long Jaw Fenestrated Johann Grasper	Φ3*200mm
LS6023	Monopolar Extra Long Jaw Fenestrated Johann Grasper	Φ3*280mm
LS6023L	Monopolar Extra Long Jaw Fenestrated Johann Grasper	Φ3*340mm
LS6024S	Monopolar Blunt Tip Atraumatic Grasper	Φ3*200mm
LS6024	Monopolar Blunt Tip Atraumatic Grasper	Φ3*280mm
LS6024L	Monopolar Blunt Tip Atraumatic Grasper	Φ3*340mm
LS6025S	Monopolar Clinch Grasper	Φ3*200mm
LS6025	Monopolar Clinch Grasper	Φ5*280mm
LS6025L	Monopolar Clinch Grasper	Φ5*340mm
LS6026S	Monopolar Rat Tooth Claw Grasper	Φ3*200mm
LS6026	Monopolar Rat Tooth Claw Grasper	Φ3*280mm
LS6026L	Monopolar Rat Tooth Claw Grasper	Φ3*340mm
LS6027S	Monopolar Babcock Grasper	Φ3*200mm
LS6027	Monopolar Babcock Grasper	Φ3*280mm
LS6027L	Monopolar Babcock Grasper	Φ3*340mm
LS6028S	Monopolar Allis Grasper	Φ3*200mm

Device Name: Monopolar Electrode Surgical Instrument Jaw Tip Family: Grasping Forceps		
Model	Device Description	Specification
LS6028	Monopolar Allis Grasper	Φ3*280mm
LS6028L	Monopolar Allis Grasper	Φ3*340mm
LS6029S	Monopolar Duckbill Grasper	Φ3*200mm
LS6029	Monopolar Duckbill Grasper	Φ3*280mm
LS6029L	Monopolar Duckbill Grasper	Φ3*340mm
LS6030S	Monopolar Wave Teeth Grasper	Φ3*200mm
LS6030	Monopolar Wave Teeth Grasper	Φ3*280mm
LS6030L	Monopolar Wave Teeth Grasper	Φ3*340mm

Table D. Models and Specifications for Monopolar Electrodes

Device Name: Monopolar Electrode Surgical Instrument Jaw Tip Family: Electrodes		
Model	Device Description	Specification
LS1031S	L Hook Coagulation Electrode	Φ5*250mm
LS1031	L Hook Coagulation Electrode	Φ5*330mm
LS1031C	L Hook Coagulation Electrode, with Cable	Φ5*330mm
LS1031L	L Hook Coagulation Electrode	Φ5*450mm
LS1031LC	L Hook Coagulation Electrode, with Cable	Φ5*450mm
LS1032S	J Hook Coagulation Electrode	Φ5*250mm
LS1032	J Hook Coagulation Electrode	Φ5*330mm
LS1032L	J Hook Coagulation Electrode	Φ5*450mm
LS1033S	Scalpel Coagulation Electrode	Φ5*250mm
LS1033	Scalpel Coagulation Electrode	Φ5*330mm
LS1033L	Scalpel Coagulation Electrode	Φ5*450mm
LS1034S	Ball Coagulation Electrode	Φ5*250mm
LS1034	Ball Coagulation Electrode	Φ5*330mm
LS1034L	Ball Coagulation Electrode	Φ5*450mm
LS1035S	Scoop Coagulation Electrode	Φ5*250mm
LS1035	Scoop Coagulation Electrode	Φ5*330mm
LS1035	Scoop Coagulation Electrode	Φ5*450mm
LS1036S	Needle Coagulation Electrode	Φ5*250mm
LS1036	Needle Coagulation Electrode	Φ5*330mm
LS1036L	Needle Coagulation Electrode	Φ5*450mm
LS1038S	L Hook Coagulation Electrode, with Extended Insulation	Φ5*250mm
LS1038	L Hook Coagulation Electrode, with Extended Insulation	Φ5*330mm
LS1038L	L Hook Coagulation Electrode, with Extended Insulation	Φ5*450mm
LS1045S	Articulating Hook Coagulation Electrode	Φ5*250mm

Device Name: Monopolar Electrode Surgical Instrument Jaw Tip Family: Electrodes		
Model	Device Description	Specification
LS1045	Articulating Hook Coagulation Electrode	Φ5*330mm
LS1045L	Articulating Hook Coagulation Electrode	Φ5*450mm
LS6031S	L Hook Coagulation Electrode	Φ3*200mm
LS6031	L Hook Coagulation Electrode	Φ3*280mm
LS6031L	L Hook Coagulation Electrode	Φ3*340mm
LS6032S	J Hook Coagulation Electrode	Φ3*200mm
LS6032	J Hook Coagulation Electrode	Φ3*280mm
LS6032L	J Hook Coagulation Electrode	Φ3*340mm
LS6033S	Scalpel Coagulation Electrode	Φ3*200mm
LS6033	Scalpel Coagulation Electrode	Φ3*280mm
LS6033L	Scalpel Coagulation Electrode	Φ3*340mm
LS6034S	Ball Coagulation Electrode	Φ3*200mm
LS6034	Ball Coagulation Electrode	Φ3*280mm
LS6034L	Ball Coagulation Electrode	Φ3*340mm
LS6035S	Scoop Coagulation Electrode	Φ3*200mm
LS6035	Scoop Coagulation Electrode	Φ3*280mm
LS6035	Scoop Coagulation Electrode	Φ3*340mm
LS6036S	Needle Coagulation Electrode	Φ3*200mm
LS6036	Needle Coagulation Electrode	Φ3*280mm
LS6036L	Needle Coagulation Electrode	Φ3*340mm

7. Intended Use/Indications for Use

The device is a family of instruments which includes scissors, probes and forceps which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar Electrosurgical cutting and/or coagulation.

8. Substantial Equivalence

8.1 Comparison between Monopolar Electrode Surgical Instrument and K142208

Table 2. Comparison to K142208

Item	**Subject Device** Monopolar Electrode Surgical Instrument	**Predicate Device** Monopolar Laparoscopic Accessories	**Result**
Regulation No.	878.4400	878.4400	Same
Regulation Class	II	II	Same

Item	Subject Device Monopolar Electrode Surgical Instrument	Predicate Device Monopolar Laparoscopic Accessories	Result
Product Code	GEI	GEI	Same
Models	**Forceps**: Grasper Babcock Forceps Clinch Forceps Rat Tooth Forceps Johan Forceps Duckbill Forceps Dissector Forceps	**Forceps**: Grasper Babcock Forceps Clinch Forceps Rat Tooth Forceps Dissector Forceps	Similar
	Scissors	**Scissors**	
	Electrodes: Monopolar J Hook Coagulation Electrode Monopolar L Hook Coagulation Electrode	**Electrodes**: Monopolar J Hook Probe Monopolar L Hook Probe	
Intended Use/Indications for Use	The device is a family of instruments which includes scissors, probes and forceps which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar Electrosurgical cutting and/or coagulation.	The device is a family of instruments which includes scissors, probes and forceps which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar Electrosurgical cutting and/or coagulation.	Same
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 jaw tips	Handle, shaft and jaw tips	Same
Shaft Length	200mm/280mm/340mm 250mm/330mm/450mm	330mm	Similar

Item	Subject Device Monopolar Electrode Surgical Instrument	Predicate Device Monopolar Laparoscopic Accessories	Result
Sterilization	EO	EO	Same
Single Use	Yes	Yes	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-11	ISO 10993-5 ISO 10993-10 ISO 10993-11	Same
Meets the IEC 60601-2-2	Yes	Yes	Same

9. Performance Data

Verification and verification results demonstrate that the device performs as intended and that the device is substantially equivalent to the predicate devices K142208.

9.1 Biocompatibility

The biocompatibility tests were performed in accordance with the FDA recognized standards:

- 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 skin sensitization and irritation
- ISO 10993-11:2017, Biological evaluation of medical devices—Part 11: Tests for systemic toxicity

9.2 Electrical Safety

The devices subject to this submission have been tested according to the requirements of IEC 60601-1, IEC 60601-2-2, IEC 60601-2-18 and IEC 60601-1-2.

9.3 Sterility

The sterilization process has been validated under consideration of recognized standards. Testing shows that the products can be EO sterilized with a sufficient

sterility assurance level of 10^{-6} by use of standard sterilization parameters.

9.4 Packing and Shelf Life

The shelf life about the Monopolar Electrode Surgical Instrument is 3 years. The shelf life period for the device was determined through an analysis of the shelf-life stability of the materials used in the design of the device, as well as an analysis of the packaging materials and processes.

10. Clinical Testing

Substantial equivalence does not depend on clinical test data.

11. Substantial Equivalence Summary/Conclusion

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