



October 28, 2021

DANNIK
Olga Haberland
Regulatory Compliance
941 W. Morse Blvd, Suite #100
Winter Park, Florida 32789

Re: K211019

Trade/Device Name: Disposable Monopolar Laparoscopic Tips and Reusable Handles
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 27, 2021
Received: October 1, 2021

Dear Olga Haberland:

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

Indications for Use

510(k) Number (if known)
K211019

Device Name
Disposable Monopolar Laparoscopic Tips and Reusable Handles

Indications for Use (Describe)

The Disposable Monopolar Laparoscopic Tips and Reusable Handles 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.

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K211019 510(k) Summary

1. SUBMITTER'S CONTACT INFORMATION

Company: DANNIK

Address: 941 West Morse Blvd. Suite #100 Winter Park, FL 32789

Contact Person: Mrs. Olga Haberland, President & Regulatory Compliance

Phone: (407) 927-1743

2. DEVICE NAME

Trade Name – Disposable Monopolar Laparoscopic Tips and Reusable Handles

Common Name – Monopolar Laparoscopic Instruments

Regulation Number – 21 CFR 878.4400

Classification Name – Electrosurgical, Cutting & Coagulation Device and Accessories

Product Code – GEI

Device Classification – Class II

Classification Panel – General and Plastic Surgery

3. PREDICATE DEVICE

The Disposable Monopolar Laparoscopic Tips and Reusable Handles claim Substantial Equivalence to Hunan Handlike Minimally Invasive Surgery Co. Endoscopic Surgical Instruments cleared under 510(k) K171825.

4. DEVICE DESCRIPTION

The Disposable Monopolar Laparoscopic Tips and Reusable Handles are sterile packaged single use monopolar attachments intended for use in combination with the Reusable Handle. It is designed to include graspers, dissectors, forceps, and scissors, intended to grasp, manipulate, cut, and cauterize soft tissue.

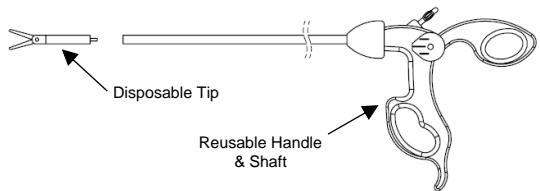
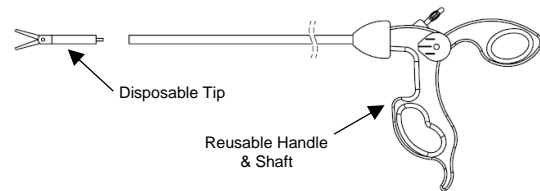
The Disposable Monopolar Laparoscopic Tips are offered in a working diameter of 5 mm with various jaw patterns including scissors, graspers, forceps and dissectors.

The Reusable Handle is supplied non-sterile and is intended to be sterilized by the user using an autoclave process. The shaft of the handle is 34 cm in length and is made from stainless steel covered with an external insulation. Handles are offered in ratcheting and non-ratcheting configurations and are intended to be connected to the sterile disposable tips. Once connected the rotation knob provides 360 degrees of rotation for the instrument shaft and jaws. The handle includes an RF Post for electrosurgery when attached to an approved electrosurgical generator to provide coagulation of tissue when used with an appropriate ground (neutral) electrode.

5. INDICATIONS FOR USE

The Disposable Monopolar Laparoscopic Tips and Reusable Handles are designed to cut, dissect, manipulate and/or cauterize various tissues during endoscopic/laparoscopic, general surgical procedures.

6. SUBSTANTIAL EQUIVALENCE TABLE

Device	Disposable Monopolar Laparoscopic Tips and Reusable Handles (510(k) TBD)	Hunan Handlike Minimally Invasive Surgery Co. Endoscopic Surgical Instruments (510(k) K171825)
Intended Use	The Disposable Monopolar Laparoscopic Tips and Reusable Handles are intended to cut, dissect, manipulate and/or cauterize various tissues during endoscopic/laparoscopic, general surgical procedures.	Same
Product Picture		
Design	The Disposable Monopolar Laparoscopic Tips and Reusable Handles are sterile single use monopolar attachments intended for use in combination with the Reusable Handle. These devices are made from biocompatible plastic and stainless steel. The handle activates the instrument jaws and scissor blades. The rotation knob provides 360 degrees of rotation for the instrument shaft and jaws. The shaft includes an external insulation that runs from the rotation knob to the instrument jaws and is provided in working diameters of 5 mm and length of 34 cm. The handle includes an RF Post for electrosurgery when attached to an approved electrosurgical generator to provide coagulation of tissue when used with an appropriate ground (neutral) electrode.	Endoscopic Surgical Instruments Tip-Detachable Type: Disposable tip and reusable shaft/handle can be disassembled but shaft cannot be disassembled from handle. Handles have ratchet and non-ratchet. Tips have 14 different models available. This product is monopolar high frequency electrode as the applied part to be used with a matching HF surgical generator with peak output voltage 3800V and frequency 0.3MHz-2MHz and neutral electrode.
Diameter	5 mm	Same
Length	34 cm	Same
Power Settings	Maximum Peak Voltage = 3800 Vp Operating Frequency = 300 to 2000 kHz Operating Current = 0.8 Arms	Maximum Peak Voltage = 3800 Vp Operating Frequency = 300 to 2000 kHz Operating Current = 0.8 Arms
Biocompatibility	Conforms to ISO 10993	Same
Sterilization	Sterilized using Ethylene Oxide for single patient use in accordance with ISO 11135 to an SAL of 10 ⁻⁶ .	Ethylene Oxide
Electrical Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18 IEC 60601-2-2	Same
Prescription Use	Yes	Yes

7. NONCLINICAL TESTS

Nonclinical testing has been conducted to verify that the Disposable Monopolar Laparoscopic Tips and Reusable Handles met all design specifications and are substantially equivalent to the predicate device. Testing included the following:

- Biocompatibility Testing performed in accordance with the following:
 - ISO 10993-1: 2018 – Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (Recognition No. 2-258)
 - ISO 10993-5:2009 – Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (Recognition No. 2-245)
 - ISO 10993-7:2008 – Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (Recognition No. 14-408)
 - ISO 10993-10:2010 – Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Recognition No. 2-174)

- ISO 10993-11:2017 – Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (Recognition No. 2-255)
- Medical Electrical Equipment Safety Testing performed in accordance with the following:
 - ANSI AAMI ES60601-1:2005/(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 60601-1:2005, MOD) (Recognition No. 19-4)
 - ANSI AAMI IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (Recognition No. 19-8)
 - IEC 60601-2-2:2017 – Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (Recognition No. 6-389)
 - IEC 60601-2-18:2009 – Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (Recognition No. 9-114)
- Aging Study
- Autoclave Sterilization Validation
- Ethylene Oxide Sterilization Validation per ISO 11135:2014 – Sterilization of health-care products - Ethylene Oxide (Recognition No. 14-529)

In addition, The Disposable Monopolar Laparoscopic Tips and Reusable Handles have been compared to the predicate device through various performance studies designed to test appearance, dimensions, corrosion resistance, operational forces, cutting efficacy and thermal effects on tissue.

Electrical performance of the device was completed following FDA guidance “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery” issued August 15, 2016. This requires testing on three different tissue types at minimum, default, and maximum generator power in order to simulate thermal spread across different tissue types. The spread is then measured under magnification, and recorded to be compared with the predicate product. Results showed an equivalent thermal spread under the same conditions across the different tissue types and power settings. Summary results are shown below.

Table 1 – Thermal Damage on Kidney Tissue

Power Level	Thermal Damage Width ($\bar{X} \pm SD$, mm)	Thermal Damage Depth ($\bar{X} \pm SD$, mm)
30W	0.42 ±0.26	3.05 ±2.10
50W	0.28 ±0.30	2.69 ±0.47
90W	0.47 ±0.36	4.43 ±1.42

Table 2 – Thermal Damage on Liver Tissue

Power Level	Thermal Damage Width ($\bar{X} \pm SD$, mm)	Thermal Damage Depth ($\bar{X} \pm SD$, mm)
30W	0.46 ±0.15	3.11 ±0.80
50W	1.41 ±1.06	4.48 ±0.53
90W	1.40 ±1.36	4.02 ±0.14

Table 3 – Thermal Damage on Muscle Tissue

Power Level	Thermal Damage Width ($\bar{X} \pm SD$, mm)	Thermal Damage Depth ($\bar{X} \pm SD$, mm)
30W	1.28 \pm 0.58	2.62 \pm 0.20
50W	1.51 \pm 0.65	3.26 \pm 0.32
90W	1.20 \pm 0.85	2.82 \pm 0.37

8. CLINICAL TESTS

There were no clinical trials performed on these devices.

9. CONCLUSIONS

The subject device has equivalent indications for use as the predicate device. There are no new technologies being added to this device from the predicate, in terms of finished device functions. The device has the same intended use and application as the predicate device.