August 16, 2021

DANNIK LLC
Mrs. Olga Haberland
President
941 West Morse Blvd., Suite 100
Winter Park, Florida 32789

Re: K210569
Trade/Device Name: Disposable Monopolar Laparoscopic Shafts 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: August 11, 2021
Received: August 11, 2021

Dear Mrs. 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

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)*
K210569

Device Name
Disposable Monopolar Laparoscopic Shafts and Reusable Handles

Indications for Use *(Describe)*
The Disposable Monopolar Laparoscopic Shafts and Reusable Handles are intended for use in endoscopic surgical procedures. It is a family of instruments which includes graspers, dissectors, and scissors, which are intended to be used to grasp, manipulate, cut, and cauterize soft tissue.

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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K210569
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 Shafts 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 Shafts and Reusable Handles claim Substantial Equivalence to GENICON X-Surge laparoscopic instruments cleared under 510(k) K171752.

4. DEVICE DESCRIPTION

The Disposable Monopolar Laparoscopic Shafts 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, and scissors, intended to grasp, manipulate, cut, and cauterize soft tissue.

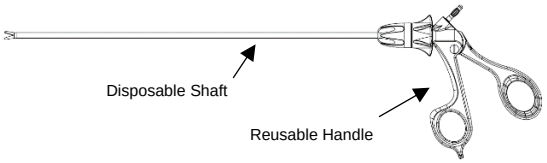
The Disposable Monopolar Laparoscopic Shafts are offered in working diameters of 3 to 5 mm and lengths between 20 to 45 cm. The shaft is made from aluminum covered with a fluorinated ethylene polypropylene external insulation. The shaft is attached to the handle using the locking knob and a stainless-steel drive rod which connects to the jaws and interacts with the handle activation rod.

The Reusable Handle is supplied non-sterile and in intended to be sterilized by the user using an autoclave process. Handles are offered in ratcheting and non-ratcheting configurations and are intended to be connected to the sterile disposable shaft. 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 Shafts and Reusable Handles are intended for use in endoscopic surgical procedures. It is a family of instruments which includes graspers, dissectors, and scissors, which are intended to be used to grasp, manipulate, cut, and cauterize soft tissue.

6. SUBSTANTIAL EQUIVALENCE TABLE

Device	Disposable Monopolar Laparoscopic Shafts and Reusable Handles (510(k) K210569)	GENICON X-Surge (510(k) K171752)
Intended Use	Endoscopic surgical procedures. It is a family of instruments which includes graspers, dissectors, and scissors, which are intended to be used to grasp, manipulate, cut, and cauterize soft tissue.	Same
Product Picture		
Design	The Disposable Monopolar Laparoscopic Shafts 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, aluminum 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 locking knob to the instrument jaws and is provided in working diameters of 3 to 5 mm and lengths of 20 to 45 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.	GENICON X-Surge instrumentation line is composed of single use sterile instruments (Reposable handle option available), made from biocompatible plastic, aluminum and stainless steel. When combined the working length is 20cm to 45cm. Current may be supplied by an approved electrosurgical generator which provides the ability for the coagulation of tissue when used with an appropriate ground electrode.
Diameter	3-5mm	Same
Length	20-45 cm	Same
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
Prescription Use	Yes	Yes

7. NONCLINICAL TESTS

Nonclinical testing has been conducted to verify that the Disposable Monopolar Laparoscopic Shafts 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)
  - 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 - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)] (Recognition No. 14-529)

In addition, The Disposable Monopolar Laparoscopic Shafts and Reusable Handles have been compared to the predicate device through various performance studies designed to test visual/operational use, performance and electrical safety and effectiveness.

Cut performance across different mediums using the predicate as a baseline was completed in order to compare any instances of slipping, overall cut length across testing mediums, and scissor opening. Testing showed the Disposable Monopolar Laparoscopic Shafts and Reusable Handles devices performed equivalent to the predicate product.

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.

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.