June 9, 2020

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

Re: K201063
Trade/Device Name: DANNIK Disposable Monopolar Laparoscopic Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 8, 2020
Received: May 12, 2020

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

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)*
K201063

Device Name
DANNIK Disposable Monopolar Laparoscopic Instrument

Indications for Use *(Describe)*
The DANNIK Disposable Monopolar Laparoscopic Instrument have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of 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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Special 510(k) Summary

1. SUBMITTER'S CONTACT INFORMATION

DANNIK
Address: 941 West Morse Blvd. Suite #100 Winter Park, FL 32789
Phone: (407) 745-1698
Name: Olga Haberland, Regulatory Compliance

2. DEVICE NAME

Trade Name – DANNIK Disposable Monopolar Laparoscopic Instruments
Common Name – Disposable 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. SUBSTANTIALLY EQUIVALENT DEVICE

The DANNIK Disposable Monopolar Laparoscopic Instruments were originally cleared under 510(k) K193019, which claimed Substantial Equivalence to Ethicon Endo-Surgery Endopath Endoscopic Instruments cleared under 510(k) K984240.

4. DEVICE DESCRIPTION

The working diameter of these devices has been reduced from 5mm to 3mm, whereas the original submission only included a 5mm working diameter. Device package labeling was been updated with the new Order Codes and Device Sizes and IFU has been updated with below device description. No other changes have been made to the information on the labeling, including warnings, operating steps, etc. No other changes have been made to these devices to date since the original clearance.

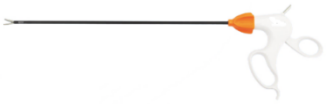
K193019 Cleared Product Codes		Additional Device Product Codes	
Code	Description	Code	Description
DMP5910	Disposable monopolar 5mm Scissor	DMP3910	Disposable monopolar 3mm Scissor
DMP5920	Disposable monopolar 5mm Autraumatic Fenestrated Grasper	DMP3920	Disposable monopolar 3mm Autraumatic Fenestrated Grasper
DMP5905	Disposable Monopolar 5mm Curved Maryland Dissector	DMP3905	Disposable Monopolar 3mm Curved Maryland Dissector

The DANNIK Disposable Monopolar Laparoscopic Instruments are sterile single-use devices consisting of a handle, rotator knob and shaft. The handle activates the instrument jaws and scissor blades. The rotator knob provides 360 degrees of rotation for the instrument shaft and jaws. The shaft includes an external insulation that runs from the rotator knob to the instrument jaws and is provided in working diameters of 3 to 5 mm and lengths up to 33 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.

5. INDICATIONS FOR USE

The DANNIK Disposable Monopolar Laparoscopic Instrument have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissue.

6. TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICE COMPARED TO THE PREDICATE DEVICE

Device	DANNIK Disposable Monopolar Laparoscopic Instruments with modified working diameter (510(k) TBD)	DANNIK Disposable Monopolar Laparoscopic Instruments (K193019)
Intended Use	The DANNIK Disposable Monopolar Laparoscopic Instrument have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissue.	Same
Product Picture		
Design	The DANNIK Disposable Monopolar Laparoscopic Instruments are sterile single-use devices consisting of a handle, rotator knob and shaft. The handle activates the instrument jaws and scissor blades. The rotator knob provides 360 degrees of rotation for the instrument shaft and jaws. The shaft includes an external insulation that runs from the rotator knob to the instrument jaws and is provided in working diameters of 3 to 5 mm and lengths up to 33 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.	The DANNIK Disposable Monopolar Laparoscopic Instruments are sterile single-use devices consisting of a handle, rotator knob and shaft. The handle activates the instrument jaws and scissor blades. The rotator knob provides 360 degrees of rotation for the instrument shaft and jaws. The shaft includes an external insulation that runs from the rotator knob to the instrument jaws and is provided in working diameter of 5 mm and lengths of 33 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.
Diameter	3 and 5mm	5mm
Biocompatibility	No Change	Conforms to ISO 10993
Sterilization	No Change	Sterilized using Ethylene Oxide for single patient use in accordance with ISO 11135 to an SAL of 10^-6.
Prescription Use	Yes	Yes

7. NONCLINICAL TESTS

Risk analysis was conducted to assess the impact of the change on the subject device using internal design control procedures. Assessments were completed for the risk associated with Electromagnetic Energy as related to the basic safety and essential performances as detailed in IEC 60601-1 and appropriate collateral and/or particular standards. Dimensional Analysis and verification of the shaft flexural strength was completed, which showed that the devices met the same requirements as the predicate device.

Details on ANNEX A

There was no impact the device sterilization, biocompatibility or packaging as included in the original submission.

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.