March 4, 2020

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

Re: K193019
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: February 18, 2020
Received: February 24, 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)*
K193019

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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510(k) /Summary

1. Contact Information
   DANNIK
   941 West Morse Blvd.
   Suite #100
   Winter Park, Florida 32789
   Phone: (407) 745-1698
   Olga Haberland, Regulatory Compliance
   January 30, 2020

2. Device Name
   - Trade Name – DANNIK Disposable Monopolar Laparoscopic Instrument
   - Common Name: Disposable Monopolar Laparoscopic Instrument
   - Classification Name : Electrosurgical, Cutting & Coagulation Device and Accessories
   - Classification: Class II General and Plastic Surgery Devices GEI, 21 CFR878.4400

Performance Standards: Devices are manufactured according to Good Manufacturing Practices (G.M.P.), Association for Advancement of Medical Instrumentation (A.AM.I.) and American Society for Testing and Materials (A.S.T.M.) requirements and applicable Harmonized Standards ISO 13485.

3. Substantially Equivalent Device
   - Legally Marketed (unmodified Devices):
   - Ethicon Endo-Surgery Endopath Endoscopic Instrument FDA 510K (K984240)

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4. Device Description

The DANNIK Disposable Monopolar Laparoscopic Instrument consists of Handle which activates the instruments jaws and scissor blades, Rotator knob that provides 360 degrees rotation , both handle and rotation knob are made of ABS thermoplastic, and a Shaft made from Medical grade Stainless Steel and insulated with high-density polyethylene PE. 5mm in diameter with a working length of 33cm. RF Post for electrosurgery when attached to an approved electrosurgical generator to provide coagulation of tissue when used with appropriate ground electrode.

This device is packaged and sterilized for single use only. Do NOT re-use, reprocess or resterilize. Discard after use with care.

Biocompatibility Conforms to ISO 10993
Prescription Only Yes
Sterilized by ETO (Ethelyn Oxide)

5. 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.

6. Technological Characteristics of the Subject Device Compared to the Predicate Device

Comparison of Technological Characteristics: DANNIK Disposable Monopolar Laparoscopic Instrument is substantially equivalent to 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.

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Device	Dannik Disposable Monopolar Laparoscopic Instrument	Ethicon Endo-Surgery Endopath Endoscopic Instrument FDA 510K (K984240)
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		
Device Description	The DANNIK Disposable Monopolar Laparoscopic Instrument consists of Handle which activates the instruments jaws and scissor blades, Rotator knob that provides 360 degrees rotation to shaft; both handle and rotation knob are made of ABS thermoplastic, and a Shaft 5mm in diameter with a working length of 33cm made from Medical grade Stainless Steel and insulated with high-density polyethylene PE. 5mm in diameter with a working length of 33cm. RF Post for electrosurgery when attached to an approved electrosurgical generator to provide coagulation of tissue when used with appropriate ground electrode.	Same/Equivalent "The Instruments have a rotating insulated shaft with a diameter of 3mm, 5mm or 10mm. The Rotation knob located on the handle rotates the shaft 260 degreed in either direction. The ring handles are compressed and released to activate the instrument jaws or scissor blades. Each of the curved scissors and dissectors has a monopolar cautery connector that extends from the top of the handle. The connector is used for electrosurgery when properly attached to a standard cautery cable and proper generator
Classification	Class II General and Plastic Surgery Devices GEI, 21 CFR878.4400	Same

Diameter	5mm x 33cm	Same (also offers additional diameters)
Materials	**Non-Patient Contact:** • ABS Thermoplastic- **Patient Contact:** • Stainless Steel • PE (Polyethylene)	Unknown
Sterilization	Ethylene Oxide (ETO) I.S.O 11135-1	Unknown
Prescription Only	Yes	Yes
Biocompatibility	Conforms to ISO 10993	Unknown

7. Non-Clinical Tests

DANNIK Disposable Monopolar Laparoscopic Instrument has been evaluated by Design Engineers, through performance and functionality evaluations that include Thermal effects on Tissue Connection strength, clamping performance , cable connection, open and close performance, Hardness , corrosion resistance and outward.

8. Clinical Tests
   No Clinical trials performed on the DANNIK Disposable Monopolar Laparoscopic Instrument

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.

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