November 19, 2019

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

Re: K192643
Trade/Device Name: DANNIK Laparoscopic Suction Irrigation System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 11, 2019
Received: October 17, 2019

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)*
K192643

Device Name
DANNIK Laparoscopic Suction Irrigation System

Indications for Use *(Describe)*
The DANNIK Laparoscopic Suction Irrigation System is indicated for use in patients undergoing a laparoscopic surgical procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to evacuate blood, and tissue debris from the surgical site

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
   September 15, 2019

2. Device Name
   - Trade Name – DANNIK Laparoscopic Suction Irrigation System
   - Common Name: laparoscopic Suction Irrigation System
   - Classification Name – Endoscope and Accessories (21 CFR 876.1500, Product Code GCJ)
3. Substantially Equivalent Device
   - Legally Marketed (unmodified Devices): The Unimax Suction Irrigation Set FDA 510K (K103509)
4. Device Description
   The DANNIK Laparoscopic Suction Irrigation System is indicated for use in patients undergoing a laparoscopic surgical procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris from the surgical site.

   The system consists of a hand piece equipped with two trumpet style valves, a probe and connecting lines of tubing, one set designated to attach to supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure.

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

5. Intended Use
   The DANNIK Laparoscopic Suction Irrigation System is indicated for use in patients undergoing a laparoscopic surgical procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to evacuate blood, and tissue debris from the surgical site.

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

AREA	DANNIK K192643	Unimax K103509
Intended Use	Laparoscopic Surgery	Same
Handpiece Design	Trumpet Valve Assembly	Same
Probe Length	33cm (330mm)	Same Unimax also offers additional probe lengths.
Materials	Probes: Medical Grade Stainless Steel	Unknown
	Handpiece: Poly Carbonate	Unknown
	Seals: Silicone	Unknown

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	Tubing: PVC	Unknown
Performance Testing	There are no US FDA performance standards for these products.	Same
Sterilization	Ethelene Oxide I.S.O. 11135-1	Unknown
Prescription Only	Yes	Same
Biocompatibility	Conforms to ISO 10993	Unknown

Dannik will NOT be offering electrical probes as offered by 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.

7. Non-Clinical Tests
   The DANNIK Laparoscopic Suction Irrigation System has been evaluated by our Design Engineer, through performance studies and bench testing which included determining and verifying appropriate fluid flow rates and valve seal integrity. Testing showed that the devices met the same requirements as the predicate device.

8. Clinical Tests
   There were no clinical trials performed on the DANNIK Laparoscopic Suction Irrigation System

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9. Conclusions
   The subject device has equivalent indications for use as the predicate device. The technological characteristics, non-clinical testing and performance and bench testing of the DANNIK Laparoscopic Suction Irrigation Device show that the device is as safe, as effective, and meets the same performance standard. Therefore, the proposed DANNIK Laparoscopic Suction Irrigation Device is substantially equivalent to the predicate.

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