March 12, 2025

Dannik, LLC
Olga Haberland
President
941 W Morse Blvd. Suite 100
Winter Park, FL 32789

Re: K250411
Trade/Device Name: DANNIK® Laparoscopic Single-Use Poly Specimen Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 13, 2025
Received: February 14, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.03.12 22:31:22 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250411

Device Name

DANNIK® Laparoscopic Single-Use Poly Specimen Retrieval System

Indications for Use *(Describe)*

The DANNIK® Laparoscopic Single-Use Poly Specimen Retrieval Devices are indicated for use as a receptacle for the collection and extraction of tissue, organs, and calculi during general and laparoscopic surgery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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www.dannik.us

510(k) TBD
510(k) SUMMARY

1. SUBMITTER'S CONTACT INFORMATION

Company: DANNIK, LLC
Address: 941 West Morse Blvd. Suite #100 Winter Park, FL 32789
Contact Person: Olga Haberland, President
Phone: (407) 745-1698

2. DEVICE NAME

Trade Name – DANNIK® Laparoscopic Single-Use Poly Specimen Retrieval System
Common Name – Retrieval Bag, Specimen Retrieval Bag
Regulation Number – 21 CFR 876.1500
Classification Name – Laparoscope, General & Plastic Surgery
Product Code – GCJ
Device Classification – Class II
Classification Panel – General and Plastic Surgery

3. PREDICATE DEVICE

The DANNIK® Laparoscopic Single-Use Poly Specimen Retrieval Devices claim Substantial Equivalence to the Unimax Specimen Retrieval System cleared under 510(k) K103510.

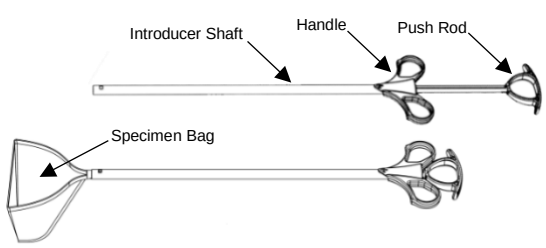
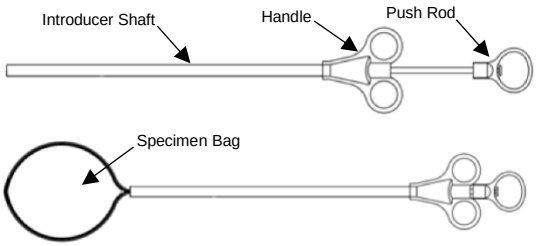
4. DEVICE DESCRIPTION

The DANNIK® Laparoscopic Single-Use Poly Specimen Retrieval System are sterile single patient use devices, which comprise of a flexible plastic bag with a deployment mechanism. The bag is supplied pre-loaded in the introducer assembly and consists of a large, easily accessible opening and a closure suture that facilitates closure of the specimen bag after the specimen(s) have been collected. The deployment mechanism consists of a push-pull rod and an introducer assembly. The deployment mechanism allows for easy insertion through the cannula and full deployment of the bag with the use of the biasing arms.

5. INDICATIONS FOR USE

The DANNIK® Laparoscopic Single-Use Poly Specimen Retrieval Devices are indicated for use as a receptacle for the collection and extraction of tissue, organs, and calculi during general and laparoscopic surgery.

6. SUBSTANTIAL EQUIVALENCE TABLE

Category	Subject Device	Primary Predicate
Device	DANNIK® Laparoscopic Single-Use Poly Specimen Retrieval System (510(k) TBD)	Unimax Specimen Retrieval System (510(k) K103510)
Intended Use	The DANNIK® Laparoscopic Single-Use Poly Specimen Retrieval Systems are intended to be used as a receptacle for the collection and extraction of tissue, organs, and calculi during general and laparoscopic surgery.	The Unimax Specimen Retrieval Systems are intended to be used as a receptacle for the collection and extraction of tissue, organs, and calculi during general and laparoscopic surgery.
Product Picture		
Design	These devices include a handle attached to an introducer shaft with the specimen bag pre-loaded inside designed to fit down standard 5 to 15mm trocar sheaths. Advancing the push rod deploys the bag from the stored position into the operating field. Metal arms secured to the distal end of the push rod automatically open the mouth of the bag upon deployment providing a large easily accessible opening to capture the tissue. Retracting the push rod removes the arms and simultaneously cinches the closure suture to fully close the mouth of the bag.	Same
Bag Volume	120 to 1500 mL	Same
Introducer Diameter	5, 10 and 12mm	Same
Biocompatibility	Conforms to ISO 10993	Unknown
Sterilization	Sterilized using Ethylene Oxide for single patient use in accordance with ISO 11135 to an SAL of 10^-6.	Sterilized using Ethylene Oxide
Prescription Use	Yes	Yes
Intended Environment	Professional Healthcare Facility (Surgical Room or Operating theatre)	Same

7. NONCLINICAL TESTS

Nonclinical testing has been conducted to verify that these devices 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 10993-10:2021 – Biological evaluation of medical devices - Part 10: Tests for skin sensitization (Recognition No. 2-296)
  - ISO 10993-11:2017 – Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (Recognition No. 2-255)

  - ISO 10993-23:2021 – Biological evaluation of medical devices - Part 10: Tests for irritation (Recognition No. 2-291)
- Aging Study
- Ethylene Oxide Sterilization Validation per ISO 11135:2014 – Sterilization of health-care products - Ethylene Oxide (Recognition No. 14-529)

In addition, these devices have been compared to the predicate device through various performance studies designed to test the general device operation and bag opening, volume, integrity and seam strength.

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.