April 21, 2020

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

Re: K200053
Trade/Device Name: DANNIK Specimen Retrieval System (Bag Only)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 6, 2020
Received: January 10, 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)*
K200053

Device Name
DANNIK Specimen Retrieval System

Indications for Use *(Describe)*
The DANNIK Specimen Retrieval System is indicated for use in surgical procedures to capture organs or tissue to be removed from the body cavity during Laparoscopic Surgery via extracorporeal manual morcellation.

The DANNIK Specimen Retrieval System is contraindicated for laparoscopic power morcellation during gynecologic procedures. The DANNIK Specimen Retrieval System is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

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.

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www.dannik.us

510(K) SUMMARY

1. Contact Information
   DANNIK
   941 West Morse Blvd. Suite #100 Winter Park, FL 32789
   Phone: (407) 745-1698
   Olga Haberland, Regulatory Compliance
   January 4, 2020

2. Device Name
   - Trade Name – DANNIK Specimen Retrieval System
   - Common Name – Retrieval Bag, Specimen Retrieval Bag
   - Regulation Number – 876.1500
   - Classification Name – Laparoscope, General & Plastic Surgery
   - Product Code: GCJ
   - Classification: Class II
   - Classification Panel: General & Plastic Surgery

3. Substantially Equivalent Device
   - Legally Marketed (Unmodified Devices):
     - The Espiner Tissue Retrieval System
     - 510(k) K111845

4. Description
   The DANNIK Specimen Retrieval System are sterile single patient use devices, which comprise of a flexible plastic bag with and without a deployment mechanism. The bag 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 the bag with the use of the biasing arms.

5. Indications for Use
   The DANNIK Specimen Retrieval System is indicated for use in surgical procedures to capture organs or tissue to be removed from the body cavity during Laparoscopic Surgery via extracorporeal manual morcellation.
   The DANNIK Specimen Retrieval System is contraindicated for laparoscopic power morcellation during gynecologic procedures. The DANNIK Specimen Retrieval System is contraindicated for use with powered cutting devices (e.g., power morcellators,

electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

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

Device	The Espiner Tissue Retrieval System (K111845)	DANNIK Specimen Retrieval System
Intended Use	Endoscope and Accessories (GCJ)	SAME
Outline		
Design	The Espiner Tissue Retrieval System consists of a family of impervious sacs which are sterile single use device that can be used alone of with a dedicated introducer system for the encaptured and removal of an organ, tissue or fluid from the body cavity during laparoscopic surgery. The sac includes introduction tab(s) or tether and a drawstring (closure suture). The introduction tab(s) are used as a contact points for the instrument (tether for attachment to the dedicated introducer) for introduction through an appropriately sized cannula. The drawstring facilitates a secure closure of the sac. The dedicated introducer comprises an introducer tube with handle, and push rod. The introducer allows for the bag to be inserted through an appropriately sized port. The push rod assembly comprises a loop on one end and biasing arms on the other, which allow the bag mouth to open upon deployment.	The DANNIK Specimen Retrieval System consist of a family of retrieval bags which are sterile single-use devices that can be used alone or with a dedicated introducer system for the capture and removal of organs or tissue from the body cavity during laparoscopic surgery. The bag includes an introduction tab or tether and a closure suture. The introduction tab is used as a contact point for the instrument (tether for attachment to the introducer assembly) for introduction through an appropriately sized cannula. The drawstring facilitates a secure closure of the bag. The introducer assembly comprises an introducer tube with handle, and push rod. The introducer allows for the bag to be inserted through an appropriately sized port. The push rod assembly comprises a loop on one end and biasing arms on the other, which allow the bag mouth to open upon deployment.
Volume	50 to 6000 mL	50 to 3000 mL
Cannula Diameter	5 to 15 mm	SAME
Performance/ Testing	Bench Testing to demonstrate safety and effectiveness to the predicate device.	Performance testing showed that the device performed equivalent or better and is therefore substantially equivalent in performance to the predicate devices
Sterilization	Sterilized using Ethylene Oxide for single patient use	SAME
Prescription Only	Yes	SAME
Biocompatibility	Unknown	Conforms to ISO 10993

The DANNIK Specimen Retrieval System is comprised of a flexible plastic bag with and without a deployment mechanism.

The bag is made from polyurethane and/or rip-stop nylon 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 bags come in sizes from 50 to 3000 mL.

The deployment mechanism consists of a push-pull rod and introducer assembly. The push-pull rod consists of a handle, shaft and biasing arms and is made from a combination of Stainless Steel, Nitinol, ABS, and PC. The introducer assembly consists of a tube and handle and is made from ABS and/or PC. The deployment mechanism allows easy insertion through the cannula and full deployment the bag with the use of the metallic biasing arms. Introducers range from 5 to 15 mm in diameter.

This device is packaged and sterilized for single use only. Do not re-use, reprocess, or re-sterilize. Discard after use.

There are no FDA performance standards for these products. The sterilization is performed by Ethylene Oxide per ISO 11135:2014. This device is available by Prescription Only for use in a Hospital Operating Room. This device is compliant with FDA Class II requirements for ISO 10993.

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7. Nonclinical Tests
   The DANNIK Specimen Retrieval System have been determined to be substantially equivalent to the Espiner Tissue Retrieval System through performance studies and bench testing which included determining and verifying appropriate introduction forces, seam strengths, tests for fluid permeability, open/closure forces and general operation. Testing showed that the devices met the same requirements as the predicate device.

   Validation of the Ethylene Oxide sterilization process was accomplished according to ISO 11135 to provide a SAL of 10^{-6}. Validation of the Ethylene Oxide process remains unchanged from the original submission.

   Packaging for these devices was designed and complies with the requirements of ISO 11607 series of standards.

   Device biocompatibility was evaluated in accordance with ISO 10993-1 and relevant sub-parts for device, given the nature and duration of patient contact.

8. Clinical Tests
   There were no clinical trials performed on the DANNIK Specimen Retrieval System.

9. Conclusions
   Based on the indications for use and technological characteristics, the DANNIK Specimen Retrieval System has shown to be substantially equivalent to the predicate device.

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