April 1, 2024

Ximedica
% Valerie Defiesta-Ng
Vice President Regulatory Affairs
Veranex, Inc.
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K240635
Trade/Device Name: ENDOCOLLECT Specimen Retrieval Bag, 8mm, ENDOCOLLECT Specimen Retrieval Bag, 12mm, ENDOCOLLECT Specimen Retrieval Bag, 15mm
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 6, 2024
Received: March 6, 2024

Dear Valerie Defiesta-Ng:

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.

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2024.04.01 13:47:37 -04'00'

Mark Trumbore, 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)*

Device Name

ENDOCOLLECT Specimen Retrieval Bag, 8mm;
ENDOCOLLECT Specimen Retrieval Bag, 12mm;
ENDOCOLLECT Specimen Retrieval Bag, 15mm

Indications for Use *(Describe)*

The ENDOCOLLECT Specimen Retrieval Bag is indicated for use in laparoscopic procedures to capture organs or tissue to be removed from the body cavity.

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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510(k) #:

510(k) Summary

Prepared on: 2024-03-05

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Ximedica
Applicant Address	55 Dupont Drive Providence RI 02907 United States
Applicant Contact Telephone	401-330-5956
Applicant Contact	Ms. Corie Vazquez
Applicant Contact Email	corie.vazquez@veranex.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	ENDOCOLLECT Specimen Retrieval Bag, 8mm; ENDOCOLLECT Specimen Retrieval Bag, 12mm; ENDOCOLLECT Specimen Retrieval Bag, 15mm
Common Name	Endoscope and accessories
Classification Name	Laparoscope
Regulation Number	876.1500
Product Code(s)	GCJ

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232519	ENDOCOLLECT Specimen Retrieval Bag	GCJ

Device Description Summary 21 CFR 807.92(a)(4)

The ENDOCOLLECT Specimen Retrieval Bag ("ENDOCOLLECT") is a disposable device used as a receptacle for the collection and extraction of tissue specimens during laparoscopic surgery and is intended to be used with an endoscopic trocar. ENDOCOLLECT is comprised of a flexible plastic bag with a large, easily accessible opening, a spring finger, deployment shaft, shaft handle, and an insertion tube. In the fully deployed condition, the specimen bag opening is maintained during the retrieval of a specimen. When the specimen is placed in the bag, the bag is closed with the cinch cord and the device may be removed from the body.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The ENDOCOLLECT Specimen Retrieval Bag is indicated for use in laparoscopic procedures to capture organs or tissue to be removed from the body cavity.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the proposed device are the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The modifications outlined in this Special 510(k) premarket notification do not raise different questions of safety or effectiveness as demonstrated by performance testing using the same methods that were utilized for the predicate device. Furthermore, these changes (1) do not affect the intended use or (2) alter the fundamental scientific technology of the device. The modified devices retain the same core technological characteristics as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

All necessary performance testing was conducted on the ENDOCOLLECT Specimen Retrieval Bag to support a determination of substantial equivalence to the predicate device.

Testing included:
- Nonclinical Bench Testing
  - o Force and Volume Testing
  - o Durability Testing
  - o Puncture Testing
  - o Spring Finger Deflection Testing
  - o Weight Capacity and Air Leak Testing
- Sterilization Validation
- Shelf-Life Testing
- Transportation Testing
- Usability Validation Testing

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the ENDOCOLLECT Specimen Retrieval Bag meet the established specifications necessary for consistent performance during its intended use. In addition, the results of the performance testing demonstrate that the differences in technological characteristics between the ENDOCOLLECT Specimen Retrieval Bag do not raise different questions of safety and effectiveness when compared to the predicate device.

Clinical testing was not required to demonstrate substantial equivalence to the predicate device.

Nonclinical performance testing has been performed on the modified devices to evaluate the overall performance. The collective results confirm that the modified devices meet its specifications and requirements for its intended use. The modified ENDOCOLLECT Specimen Retrieval Bag is substantially equivalent to the predicate device.