March 19, 2018

Genicon, Inc
Katlyn Kachman
Regulatory Compliance
6869 Stapoint Court
Suite 114
Winter Park, Florida 32792

Re: K180579
Trade/Device Name: EZee Retrieval
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 1, 2018
Received: March 5, 2018

Dear Ms. Kachman:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K180579

Device Name
EZee Retrieval

Indications for Use *(Describe)*
The GENICON EZee Retrieval 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.

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510(k) Summary per 21 CFR 807.92

1. Contact Information
   GENICON
   6869 Stapoint Court, Suite 114, Winter Park, FL 32792
   Phone (407) 657-4851 Fax (407) 677-9773
   Katlyn Kachman, Regulatory Compliance
   March 19, 2018

2. Device Name
   GENICON EZee Retrieval

3. Substantially Equivalent Device
   GENICON EZEE Retrieval [K162059]

4. Description
   The GENICON EZee Retrieval is comprised of a flexible plastic bag with a large, easily accessible opening, an actuation rod with thumb ring handle, finger rings, string and closure suture, and an introducer shaft. In the fully deployed condition, the bag opening is maintained in a fully-open position by a metallic rim, and the size of the specimen bag is 4” x 5” with a volume of 230ml. A string with a closure suture facilitates closure of the specimen bag after the specimen had been collected. This device is disposable device packaged and sterilized for single use only. Do not re-use, reprocess, or re-sterilize. Discard after use.

5. Indications for Use
   The GENICON EZee Retrieval is indicated for use in laparoscopic procedures to capture organs or tissue to be removed from the body cavity.

6. Technical Specifications
   The GENICON EZee Retrieval is intended for Laparoscopic Surgery (GCJ) and contains a Bag, Biasing Arms, Introducer, Closure Suture/String, Handle and Actuation/Deployment Shaft. The shaft diameter is 10mm and is composed of PC while the Bag is Plastic and the Introducer is Stainless Steel. 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.

Device	Genicon Ezee Retrieval 510 (k) K162059	Genicon Ezee Retrieval (with updated technology change) 510 (k) K180579
Intended use	Laparoscopic Surgery (GCJ)	Laparoscopic Surgery (GCJ)
Design	Bag, Biasing Arms, Introducer, Closure Suture/String, Handle, Actuation/Deployment Shaft	Same
Introducer diameter	10mm	10mm
Materials	Shaft – ABS/PC Bag – TPU	Same
Performance	There are no FDA performance standards for these products. Bench testing and clinical evaluation performed.	SAME Additional performance bench testing for multiple deployment evaluation
Sterilization	Ethylene Oxide per ISO 11135-1:2014	SAME
Where used	Hospital operating room	SAME
Prescription only	YES	YES
Biocompatibility	Compliant with FDA class II requirements for ISO 10993	SAME

7. Nonclinical Tests
   The GENICON EZee Retrieval has been evaluated by our Chief Technical Officer and Design Engineers through performance studies and bench testing which included Deployment Force, Seam Strength, and Puncture Force. In addition, testing was performed to simulate multiple specimen captures to see if there were any performance concerns. The test shows that after there are no concerns of safety or effectiveness of the device after multiple uses.

   In order to inspect for leaks after simulating multiple specimen captures, the sample pouch was removed from the device and the water-impregnated specimen was placed in the open bag. The sample was slowly rolled top down as the internal pressure continued to rise. The bag was visually inspected for bursts and tears during this process and found no water on the exterior of the bag.

8. Clinical Tests
   There were no clinical trials performed on the GENICON EZee Retrieval.

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