



August 21, 2018

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

Re: K181791

Trade/Device Name: GENICON Simple Specimen Retrieval Bag (SimplyStrong and SimplyEZee)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 29, 2018
Received: July 5, 2018

Dear Katlyn 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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

Indications for Use

510(k) Number (if known)
K181791

Device Name
GENICON SIMPLE SPECIMEN RETRIEVAL BAG (SIMPLYSTRONG AND SIMPLYEZEE)

Indications for Use (Describe)
THE GENICON SIMPLE SPECIMEN 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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006-1

510(k) Summary

1. Contact Information

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 Phone (407) 657-4851 Fax (407) 677-9773
 Katlyn Kachman, Regulatory Compliance
 August 21, 2018

2. Device Name

- Trade Name – GENICON SimplyStrong and SimplyEZee
- Common Name – Simple Specimen Retrieval Bag
- Classification Name – Endoscope and Accessories (21 CFR 876.1500, Product Code GCJ)

3. Substantially Equivalent Device

Legally Marketed (unmodified) Devices: The Espiner Tissue Retrieval System (K111845)

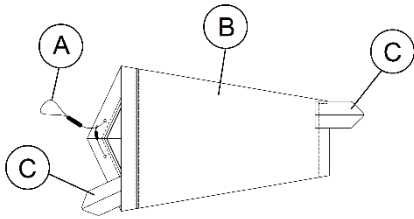
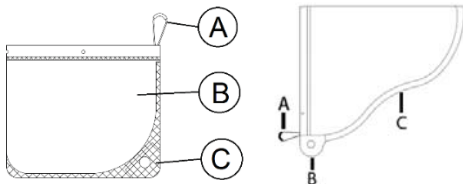
4. Device Description

The Genicon Simple Specimen Retrieval Bags are comprised of a flexible plastic bag with and without a deployment mechanism. The deployment mechanism consists of a push rod and handle. The deployment mechanism allows for easy insertion through the cannula to deploy the bag within the body cavity. Bags without a deployment mechanism may be introduced using a standard atraumatic grasper or dissector. 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. This device is packaged and sterilized for single use only. Do not re-use, reprocess, or re-sterilize. Discard after use.

5. Intended Use

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

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

Device	The Espiner Tissue Retrieval System (K111845)	GENICON SimplyStrong and SimplyEZee Retrieval System
Intended Use	Endoscope and Accessories (GCJ)	SAME
Component Design	 <p>A. Closure Suture B. Bag C. Introduction Tab(s)</p>	 <p>A. Closure Suture B. Bag C. Introduction Tab(s)</p>
Design	<p>The Espiner Tissue Retrieval System consists of a family of impervious sacs which are sterile single use device that can be used alone or with a dedicated introducer system for the encapsulated and removal of an organ, tissue or fluid from the body cavity during laparoscopic surgery.</p> <p>The sac includes introduction tab(s) and a drawstring (closure suture). The introduction tab(s) are used as a contact points for the instrument or push rod for</p>	<p>The GENICON Simple Specimen Retrieval Bags 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.</p> <p>The bag includes an introduction tab and a closure suture. The introduction tab is used as a contact point for the instrument or push rod for introduction through an</p>

	introduction through an appropriately sized cannula. The drawstring facilitates mouth opening as well as secure closure of the sac. Devices are X-ray opaque.	appropriately sized cannula. The drawstring facilitates mouth opening as well as secure closure of the sac. Bags incorporates radiopaque markers allowing for x-ray detection in case the bag is left inside the patient after the surgical procedure.
Volume	50 to 6000 mL	50 to 3000 mL
Cannula Diameter	5 to 15 mm	SAME
Performance/ Testing	There are no FDA performance standards for these products. Bench Testing to demonstrate safety and effectiveness to predicate device.	Performance testing showed that the device performed equivalent or better and is therefore substantially equivalent in performance to the predicate devices
Sterilization	Sterile/Single-Use	SAME
Prescription Only	Yes	SAME
Biocompatibility	Unknown	Conforms to ISO 10993

There are no new technologies being added to the 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 GENICON Simple Specimen Retrieval Bags 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, puncture forces, tests for fluid permeability and transparency, and open/closure forces. Testing showed that the devices met the same requirements as the predicate device. Additionally, the following tests were also conducted: packaging validation, visual inspection, biocompatibility testing, and sterilization validation.

8. Clinical Tests

There were no clinical trials performed on the GENICON Simple Specimen Retrieval Bags.

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 GENICON Simple Specimen Retrieval Bags show that the device is as safe, as effective, and meets the same performance standard. Therefore, the proposed GENICON Simple Specimen Retrieval Bags are substantially equivalent to the predicate.