April 18, 2018

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

Re: K180836
Trade/Device Name: GENICON Specimen Retrieval Bag (GeniStrong)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 27, 2018
Received: March 30, 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. 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)*
K180836

Device Name
Specimen Retrieval Bag (GeniStrong)

Indications for Use *(Describe)*
The GENICON 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.

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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
   April 11, 2018

2. Device Name
   GENICON Specimen Retrieval Bag (GeniStrong)

3. Substantially Equivalent Device
   GENICON Specimen Retrieval Bag [K132375]

4. Description
   The Genicon Specimen Retrieval Bag System is comprised of a flexible plastic bag and deployment mechanism. 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. 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. Indications for Use
   The GENICON Specimen 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 Specimen Retrieval Bag System is comprised of a flexible plastic bag and deployment mechanism.

   The bag is made from polyurethane and/or rip-stop nylon and consists of a large, easily accessible opening and a polyolefin 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 or Gamma Radiation per ISO11137:2006. 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 510k Number: K132375	Genicon Re-Deployable Bag
Intended Use	Laparoscopic Surgery (GCJ)	Laparoscopic Surgery (GCJ)
Component Design	Bag, Biasing Arms, Introducer, Closure Suture, Handle, Actuation/Deployment Shaft	SAME
Introducer Diameter	5 to 15 mm	SAME
Materials	Introducer Assembly – PC, ABS, Silicone Bag – Polyolefin, PU Coated Nylon Push-Pull Rod – Stainless Steel, Nitinol, ABS	Introducer Assembly - PC, ABS, Silicone Bag - Polyolefin, PU and/or Nylon Push-Pull Rod – Stainless Steel, Nitinol, ABS, PC
Performance	There are no FDA performance standards for these products. Bench Testing and Clinical Evaluation performed,	SAME. Additional performance bench testing for increased biasing arm strength, ability for redeployment, and gamma sterilization
Sterilization	Ethylene Oxide per ISO 11135-1:2007	Ethylene Oxide per ISO 11135-1:2007 or Gamma to ISO 11137-1:2006
Where Used	Hospital Operating Room	SAME
Prescription Only	YES	SAME
Biocompatibility	Compliant with FDA Class II requirements for ISO 10993	SAME

7. Nonclinical Tests

The GENICON Specimen Retrieval line has been evaluated by our Chief Technical Officer and Design Engineers, through performance studies and bench testing which included determining and verifying appropriate introduction forces, seam strengths, puncture forces, tests for fluid permeability and transparency, open and closure forces, forces of deployment and retraction of biasing arms.

For the upgraded biasing arms benchmarking of the introduction and retraction of the GeniStrong device was performed during initial development. The increased strength in the arms used this criterion as a limit of how much the arm geometry can be changed. This in turn was modified to increase holding forces of the bag when loaded without having any detriment on the overall safety and effectiveness of the device.

For multiple deployment, tests were performed to simulate multiple specimen captures to see if there were any performance concerns. 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. The tests show that after multiple deployments there are no concerns of safety or effectiveness of the device after multiple uses.

The addition of gamma as a sterilization method has been evaluated for compatibility with materials being exposed and tested to ISO 10993, along with performance testing of the device. The performance of the critical features of the bags was done on product run up to minimum of 2 times maximum exposure. The critical performance features of the device passed all minimum acceptance currently applied to the product. From the testing, the FMEA and risks were updated

and show that there are no additional concerns of safety or effectiveness of the device. The updated biocompatibility was completed to approve second source suppliers and any updated materials for many of the materials used in production including barium thread, PU, PU coated Nylon, PP Monofilament, and Heat Shrink.

Validation of the gamma sterilization process was accomplished according to ISO 11137-1:2006 to provide a SAL of 10^{-6}. Validation of the Ethylene Oxide process remains unchanged from the original submission.

8. Clinical Tests
   There were no clinical trials performed on the GENICON Specimen Retrieval Bag (GeniStrong).

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