GENICON

JUN 12 2014 K132375

Section 2
510(k) Summary per 21 CFR 807.92

1. Contact Information
GENICON LLC
6869 Stapoint Court Suite 114, Winter Park, FL 32792
Phone (407) 657-4851 Fax (407) 677-9773
Katlyn Tissue, Quality Supervisor
July 24, 2013

2. Device Name
Trade Name: GENICON Specimen Retrieval Bag
Common Name: Single Use Specimen Retrieval Bag including sterile packaged Single-Use Specimen Retrieval Bag and Introducer
Classification: 21 CFR 876.1500 GCJ

3. Substantially Equivalent Device
Anchor Tissue Retrieval Bag 100, 10mm introducer, K061555, K091930

4. Description
The GENICON Single-Use Specimen Retrieval Bag is comprised of a flexible plastic bag with a large, easily accessible opening, a push-pull 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. A string with a closure suture facilitates closure of the specimen bag after the specimen has 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 Single-Use Specimen Retrieval Bag is indicated for use in laparoscopic procedures to capture and remove organs or tissue from the body cavity.

6. Technical Specifications
The GENICON Single-Use Specimen Retrieval Bag is intended for Laparoscopic Surgery (GCJ) and contains a Bag, Biasing Arms, Introducer, Closure Suture/String, Handle and Actuation/Deployment Shaft. The shaft diameter ranges from 5-15 mm and is composed of PC while the Bag is PU Coated Nylon (PA) and the Introducer is Stainless Steel. There are no FDA performance standards for these products; however Bench Testing and Clinical Evaluation performed (*ref. TR-12022-A and CLEV-032-A*). The sterilization is performed by Ethylene Oxide per ISO 11135-1:2007. 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.

7. Nonclinical Tests
The GENICON Specimen Retrieval Bag has been evaluated with seal strength peel, puncture resistance, and general operation testing. Successful results support a determination of substantial equivalence

8. Conclusions
Based on the indications for use and technological characteristics, the GENICON Specimen Retrieval Bag has shown to be safe and effective for its intended use and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

GENICON LLC
Ms. Katlyn Tissue
Quality Supervisor
6869 Stapoint Court, Suite 114
Winter Park, Florida 32792

June 12, 2014

Re: K132375
Trade/Device Name: GENICON Specimen Retrieval Bag
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 27, 2014
Received: March 28, 2014

Dear Ms. Tissue:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Neil R Ogden -S
2014.06.12 16:09:43 -04'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132375

Device Name
GENICON Specimen Retrieval Bag

Indications for Use *(Describe)*
The GENICON Single-Use 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."