



September 11, 2018

ConMed Corporation
Lisa Anderson
Manager, Regulatory Affairs
525 French Road
Utica, NY 13502

Re: K173822
Trade/Device Name: Anchor™ Tissue Retrieval System™ by CONMED
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 9, 2018
Received: August 10, 2018

Dear Lisa Anderson:

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,


Sharon M. Andrews -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173822

Device Name

Anchor™ Tissue Retrieval System™ by CONMED

Indications for Use (Describe)

The Anchor™ Tissue Retrieval System™ by CONMED is a sterile disposable pouch used with a dedicated introducer for the encapture and transvaginal removal of an organ or tissue during laparoscopic hysterectomy.

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) Summary of Safety and Effectiveness

Anchor™ Tissue Retrieval System™ by CONMED

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number K173822 as of September 11, 2018.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

B. Company Contact

Lisa Anderson
Manager, Regulatory Affairs
T: (941) 713-2035
F: (315) 624-3225

C. Device Name

| | |
|--------------------|--|
| Proprietary Name: | Anchor™ Tissue Retrieval System™ by CONMED |
| Common Name: | Specimen Retrieval Bag |
| Regulation Number: | 876.1500 |
| Regulation Name: | Endoscope and accessories |
| Product Code: | GCJ (laparoscope, general & plastic surgery) |
| Device Class: | II |

D. Predicate Device

| | |
|----------------------|--------------------------------|
| Primary Device Name: | Anchor Tissue Retrieval System |
| Company Name: | CONMED Corporation |
| 510(k): | K172940 |

This predicate has not been the subject to a design-related recall.

E. Device Description

The Anchor™ Tissue Retrieval System™ by CONMED is a sterile, disposable, retrieval pouch for use with a dedicated introducer for the encapture and transvaginal removal of an organ or tissue during laparoscopic hysterectomy. The Anchor™ Tissue Retrieval System™ by CONMED consists of a rip stop nylon with polyurethane laminate pouch and two stainless steel arms attached to internal pusher rod, which is connected to a handle at the end distal to the patient. Around the internal pusher rod is the introducer with handle. The introducer handle incorporates a spring-loaded button and a stop

mechanism is built into the pusher rod. There is a braided drawstring which enters the introducer with the pusher rod and loops through the rip stop nylon pouch with polyurethane laminate.

If the surgeon deems it appropriate, the Anchor™ Tissue Retrieval System™ by CONMED can be redeployed in the same single patient procedure.

F. Indications for Use

The Anchor™ Tissue Retrieval System™ by CONMED is a sterile disposable pouch used with a dedicated introducer for the encapture and transvaginal removal of an organ or tissue laparoscopic hysterectomy.

In comparison with the predicate device, the subject device is designed for the same intended use of encapture and removal of an organ and tissue from the body cavity. The devices differ in the mode of insertion and surgical procedure. The predicate is intended to be inserted into the body cavity via a laparoscopic access port and indicated for use during laparoscopic surgery. The subject device is intended to be inserted through the vaginal canal and indicated for use during laparoscopic hysterectomy.

G. Technological Characteristics

The Anchor™ Tissue Retrieval System™ by CONMED has similar technological characteristics as the predicate device in that the Anchor™ Tissue Retrieval System™ by CONMED has the same design, same deployment mechanism, and utilizes the same materials including the rip stop nylon pouch with polyurethane laminate, introducer components, and external introducer as the predicate. As with the predicate, the Anchor™ Tissue Retrieval System™ by CONMED continues to function as a single patient procedure pouch with a dedicated introducer for the encapture and removal of the organ or tissue during laparoscopic surgery. The differences in the subject device from the predicate device is that the subject device has larger dimensions than the predicate device, the shape of the introducer is different, the stainless steel used is different and the subject device will be inserted into the patient directly through a natural body orifice.

| Characteristic | Anchor™ Tissue Retrieval System™ by CONMED | Predicate Device K172940 |
|-------------------------|--|--------------------------|
| Where Used | Operating room | Same |
| Prescription Only | Yes | Same |
| Design | Specimen bag and a delivery system consisting of an introducer shaft deployment handle | Same |
| Materials | Nylon, stainless steel, polycarbonate | Same |
| Introducer Shape | Oval | Round |
| Toggle material | 420 Stainless Steel | 302 Stainless Steel |
| Mechanism to deploy bag | Automatic with compression of pusher rod | Same |

| Characteristic | Anchor™ Tissue Retrieval System™ by CONMED | Predicate Device K172940 |
|---|--|--------------------------|
| Mechanism to redeploy bag | Automatic with compression of pusher rod | Same |
| Mechanism to separate bag from introducer | Push button | Same |
| Bag volume | 6000mL | 125-1800mL |

The differences between the predicate device and the proposed device do not raise any different risks of safety or effectiveness.

H. Summary of Performance Testing

Design verification activities demonstrate the device meets design specifications. These activities include verification of bag volume, drawstring length, puncture resistance, multiple deployments, insertion/removal force, and bag burst pressure. Design validation activities consisted of simulated use in a cadaver model. Users assessed device performance including insertion, multiple deployments, device/specimen removal, clarity of instructions for use and overall reliability and quality of the device. The results of design validation testing were acceptable.

I. Conclusion

Supporting information per this premarket submission confirms that the Anchor™ Tissue Retrieval System™ by CONMED is as safe and effective for its intended use as the predicate Anchor Tissue Retrieval System™.