October 18, 2017

ConMed Corporation
Ms. Rachelle Fitzgerald
Senior Specialist, Regulatory Affairs
525 French Road
Utica, New York 13502

Re: K172940
Trade/Device Name: ANCHOR Tissue Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 25, 2017
Received: September 26, 2017

Dear Ms. Fitzgerald:

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

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)*

K172940

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 removal of an organ or tissue from the body cavity during laparoscopic surgery.

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 21 CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number _____ as of September 25, 2017.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

B. Company Contact

Rachelle Fitzgerald
Senior Specialist, Regulatory Affairs
T: (203) 799-2400 ext 8195
F: (203) 799-2401

C. Device Name

Proprietary Name:	Anchor Tissue Retrieval System™ by CONMED
Common Name:	Laparoscope, General & Plastic Surgery
Panel:	Gastroenterology/Urology
Product Code:	GCJ
Device Class:	II
Regulation Number:	876.1500

D. Predicate Device

Primary Device Name:	Anchor Tissue Retrieval System
Company Name:	CONMED Corporation
510(k):	K091930

This predicate has not been 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 removal of an organ or tissue from the body cavity during laparoscopic surgery. The Anchor Tissue Retrieval System™ by CONMED consists of a rip stop nylon pouch, two stainless steel arms attached to internal pusher rod connected to a handle at the distal end to the patient. Around the internal pusher rod is the introducer and handle. The introducer handle

incorporates a spring loaded button and 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.

Differences between the predicate device and the Anchor Tissue Retrieval System™ by CONMED are limited to the additional feature that the Anchor Tissue Retrieval System™ by CONMED is able to be redeployed within a single patient procedure.

F. Intended Use / Indications for Use

The Anchor Tissue retrieval system by CONMED is a sterile disposable pouch used with a dedicated introducer for the encapture and removal of an organ or tissue from the body cavity during laparoscopic surgery.

G. Technological Characteristics

The Anchor Tissue Retrieval System™ by CONMED has the same 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 rip stop nylon pouch, 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 use pouch with a dedicated introducer for the encapture and removal of the organ or tissue from the body cavity during laparoscopic surgery. The difference in the subject device from the predicate device is that the subject device has a new feature where, if the surgeon deems it appropriate, the Anchor Tissue Retrieval System™ by CONMED can be redeployed in the same single patient procedure. The Anchor Tissue Retrieval System™ by CONMED is safe and effective and substantially equivalent to the predicate as demonstrated by non-clinical performance testing for the same indications for use, target population, principles of operation, performance specifications, and standards for sterilization, packaging, and biocompatibility.

Characteristic	Anchor Tissue Retrieval System™ by CONMED	Predicate Device K091930
Intended Use	The Anchor Tissue retrieval system by CONMED is a sterile disposable pouch used with a dedicated introducer for the encapture and removal of an organ or tissue from the body cavity during laparoscopic surgery.	Same
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
Mechanism to deploy bag	Automatic with compression of pusher rod	Same
Mechanism to separate bag from introducer	Push button	Same

Characteristic	Anchor Tissue Retrieval System™ by CONMED	Predicate Device K091930
Performance	There are no FDA performance standards for this device. Device performance was adequately tested through bench testing methodologies.	Same
Sterilization	Ethylene Oxide per ISO 11135:2014	Same
Biocompatibility	According to ISO 10993-1:2009	Same

H. Performance Testing

Non-clinical bench and simulated use testing demonstrate the Anchor Tissue Retrieval System™ by CONMED is substantially equivalent to the predicate device with regard to indication for use, materials, technology, and performance. Design verification testing demonstrates devices comply with design specifications and applicable sections of ISO 11607-1:2006, ISO 11135:2014, ISO 10993-7:2008. Results from design validation testing performed demonstrate that the Anchor Tissue Retrieval System™ by CONMED conforms to user needs and the intended use. Risk management activities in accordance with ISO 14971 demonstrate the risks associated with the use of the Anchor Tissue Retrieval System™ by CONMED, including redeployment, are mitigated to an acceptable level. No new issues of safety of effectiveness were identified and redeployment has no impact on current device safety and effectiveness. Analyses of these activities conclude the benefits associated with the use of the Anchor Tissue Retrieval System™ by CONMED outweigh the residual risks. Material analysis and testing demonstrate the patient contacting materials are biocompatible and comply with the requirements of ISO 10993-1:2009. Redeployment verification testing determined that the Anchor Tissue Retrieval System™ by CONMED can be deployed more than once within a single patient procedure. Performance testing demonstrates that the performance of the Anchor Tissue Retrieval System™ by CONMED is substantially equivalent to the predicate device.

I. Substantial Equivalence

There are no differences between the predicate device and the proposed device regarding design, intended use, principals of operation and technical characteristics. Supporting information per this premarket submission confirms that the Anchor Tissue Retrieval System™ by CONMED does not raise any new risks of safety or effectiveness.