March 13, 3019

ConMed Corporation
Jessica Swafford
Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K183600
Trade/Device Name: Anchor Bag-Alone Tissue Retrieval System by CONMED
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 20, 2018
Received: December 26, 2018

Dear Jessica Swafford:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.03.13 06:58:00 -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183600

Device Name
Anchor Bag-Alone® Tissue Retrieval System™ by CONMED

Indications for Use *(Describe)*
The Anchor Bag-Alone® Tissue Retrieval System™ by CONMED is a sterile disposable pouch used for the encapture and removal of an organ or tissue from the body cavity during laparoscopic or minimally invasive 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 Bag-Alone® 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 _____ as of December 20, 2018.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

B. Company Contact

Jessica Swafford
Specialist, Regulatory Affairs
T: (303) 699-7600 ext. 5086
F: (303)-699-9854

C. Device Name

Proprietary Name:	Anchor Bag-Alone® 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™ by CONMED
Company Name:	CONMED Corporation
510(k):	K172940

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

E. Device Description

The Anchor Bag-Alone® Tissue Retrieval System™ by CONMED is a sterile, disposable retrieval pouch for the encapture and removal of an organ or tissue from the body cavity during laparoscopic surgery. The Anchor Bag-Alone® Tissue Retrieval System™ by CONMED consists of a ripstop nylon pouch with polyurethane laminate and a braided drawstring that loops through the ripstop nylon pouch.

Differences between the predicate device and the subject device designs are limited to the following:

- The subject device design does not incorporate the introducer with handle, pusher rod, and stainless-steel arms present in the predicate;
- The subject device is designed with nominal bag volumes of 175, 250, and 1200mL compared to the predicate device nominal bag volumes of 125, 175, 250, 1200, and 1800mL;
- The subject device is intended to be used with 10mm or larger trocar/port compared to the predicate device compatible trocar/port range which includes 8mm or larger.
- The subject device is inserted into a cannula using laparoscopic instruments compared to the predicate devices which are inserted via a dedicated introducer.

F. Intended Use / Indications for Use

The Anchor Bag-Alone® Tissue Retrieval System™ by CONMED is a sterile disposable pouch used for the encapture and removal of an organ or tissue from the body cavity during laparoscopic or minimally invasive surgery.

G. Technological Characteristics

The Anchor Bag-Alone® Tissue Retrieval System™ by CONMED is similar to the predicate device in that the pouch and drawstring materials and designs are the same as the predicate. As with the predicate, the Anchor Tissue Retrieval System™ by CONMED continues to function as a single patient/procedure use pouch 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 the removal of the introducer components. The Anchor Bag-Alone® Tissue Retrieval System™ by CONMED is safe and effective and substantially equivalent to the predicate as demonstrated by non-clinical performance testing.

Characteristic	Anchor Bag-Alone™ Tissue Retrieval System™ by CONMED	Predicate Device K172940
Intended Use	The Anchor Bag-Alone® Tissue Retrieval System™ by CONMED is a sterile disposable pouch used for the encapture and removal of an organ or tissue from the body cavity during laparoscopic or minimally invasive surgery.	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.
Where Used	Operating room	Identical
Prescription Only	Yes	Identical

Characteristic	Anchor Bag-Alone™ Tissue Retrieval System™ by CONMED	Predicate Device K172940
Design	Specimen bag and drawstring	Specimen bag and drawstring with a delivery system consisting of an introducer shaft and deployment handle and latch
Materials	Ripstop Nylon with Polyurethane Laminate, polyester yarn	Stainless-steel, polycarbonate Identical nylon, and polyester yarn
Performance	There are no FDA performance standards for this device. Device performance was adequately tested through bench testing methodologies.	Identical
Sterilization	Ethylene Oxide per ISO 11135:2014	Identical
Biocompatibility	According to ISO 10993-1:2009	Identical

H. Performance Testing

Non-clinical bench and simulated use testing demonstrated the Anchor Bag-Alone® by CONMED is substantially equivalent to the Anchor Tissue Retrieval System™ by CONMED with regard to intended use, materials, technology, and performance. Design verification testing demonstrates the devices comply with the applicable sections of ISO 11607-1:2006, ISO 11135:2014, ISO 10993-7:2008. Risk management activities in accordance with ISO 14971 demonstrate the risks associated with the use of the Anchor Bag-Alone® Tissue Retrieval System™ by CONMED are mitigated to an acceptable level. Analyses of these activities conclude the benefits associated with the use of the Anchor Bag-Alone® Tissue Retrieval System™ by CONMED outweigh the residual risks.

I. Substantial Equivalence

The differences between the predicate device and the proposed device do not raise any new risks of safety or efficacy. Supporting information per this premarket submission confirms that the Anchor Bag-Alone® Tissue Retrieval System™ by CONMED is safe and effective for its intended use and is substantially equivalent in design, intended use, principals of operation, and technical characteristics to the predicate Anchor Tissue Retrieval System™ by CONMED.