DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 10, 2015

ConMed Corporation
Anna D'Lima
Senior Specialist, Regulatory Affairs
525 French Road
Utica, NY 13502

Re: K142716
Trade/Device Name: VCARE® (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)
Regulation Number: n/a
Regulation Name: Cannula, Manipulator/Injector, Uterine
Regulatory Class: n/a
Product Code: LKF
Dated: January 12, 2015
Received: January 13, 2015

Dear Anna D'Lima,

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" (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 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,

Herbert P. Lerner -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

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)*
K142716

Device Name

VCARE® (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)

Indications for Use *(Describe)*

The ConMed VCARE® Retractor/Elevator is indicated for manipulation of the uterus, and injection of fluids or gases during laparoscopic procedures such as Laparoscopic Assisted Vaginal Hysterectomy (LAVH), Total Laparoscopic Hysterectomy (TLH), minilap, laparoscopic tubal occlusion or diagnostic laparoscopy and also maintains pneumoperitoneum by sealing the vagina once colpotomy is performed.

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.

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# 510(k) Summary of Safety and Effectiveness

## VCARE® (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator)

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 K142716 as of February 9, 2015.

### A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502
Establishment Registration: 1320894

### B. Company Contact

Anna D'Lima, RAC
Senior Specialist, Regulatory Affairs
T: (315) 624-3371
F: (315) 624-3225

### C. Device Name

| | |
|---|---|
| Proprietary Name: | VCARE® (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator) ("VCARE") |
| Common Name: | Cannula, Manipulator/Injector, Uterine |
| Panel: | Obstetrics/Gynecology |
| Product Code: | LKF |
| Device Class: | Unclassified |
| Regulation Number: | N/A |

### D. Predicate Device

| | |
|---|---|
| Device Name: | VCARE® (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator) ("VCARE") |
| Company Name: | ConMed Corporation |
| 510(k): | K071907 |

### E. Device Description

The modified VCARE® (Vaginal-Cervical-Ahluwalia's-Retractor-Elevator) ("VCARE") is a disposable, single-use device for manipulation of the uterus and cervix in surgical and diagnostic procedures. The modified VCARE consists of an insulated manipulator tube having an inflatable balloon at its distal [to user] end and an anatomically configured cannula/handle for maintaining proper attitude of the uterus at the proximal end. The insulated manipulator tube is marked with reference graduations from the distal end (centimeters). The graduations are provided as a guide for comparison to a graduated uterine sound. VCARE incorporates a cervical cup to provide manipulation of the uterus, and retraction and elevation of the cervix. There are four (4) size variations of cervical cups – Small (S), Medium (M), Large (L), and Extra-Large (XL). The cervical cups are green and provide a colpotomy guide. Sites for suturing are located on the cervical cup. Differences between the predicate

device and the modified VCARE improve device performance and functionality for uterine manipulation during the indicated procedures and are limited to:

1) New occluder design for sealing pneumoperitoneum once colpotomy is performed,
2) Improved handle design, and
3) Revised component retention mechanism and balloon length.

## F. Intended Use / Indications for Use

The ConMed VCARE® Retractor/Elevator is indicated for manipulation of the uterus, and injection of fluids or gases during laparoscopic procedures such as Laparoscopic Assisted Vaginal Hysterectomy (LAVH), Total Laparoscopic Hysterectomy (TLH), minilap, laparoscopic tubal occlusion or diagnostic laparoscopy and also maintains pneumoperitoneum by sealing the vagina once colpotomy is performed.

## G. Non-clinical Performance Testing

Non-clinical bench and simulated use testing demonstrate that the modified VCARE is substantially equivalent to the predicate device with regard to intended use/ indication for use, materials, technology, and performance. Design verification demonstrates devices comply with design specifications and applicable sections of ISO 11607-1:2006, ISO 11135-1:2007, AAMI/ANSI ST67:2011, ISO 10993-7:2008, ISO 594/1:1986, and ISO 594-2:1998. Product bench testing included component retention, balloon performance, sealing of the pneumoperitoneum, material properties, handle torque, ergonomics, and usability (human factors). Results of design validation testing performed in simulated use environments demonstrate the modified VCARE conforms to user needs and intended use. Material analysis and testing demonstrate the patient contacting materials are biocompatible and comply with the requirements of ISO 10993-1:2009. Performance testing demonstrates that the performance of the modified VCARE is substantially equivalent to the predicate device.

## H. Substantial Equivalence

**Intended Use/ Indications for Use**
There was no change to the intended use or indications for use for the VCARE product in comparison to the predicate device.

**Technological Characteristics**
As with the predicate device, the modified VCARE continues to function as a disposable, single-use device for manipulation of the uterus and cervix in surgical and diagnostic procedures. The differences in the technological characteristics of the device are improvements in functionality based on user review and feedback since the predicate product clearance. Differences between the modified VCARE and the predicate device are limited to those listed in Section E, 1-3. The differences in technological characteristics between the predicate device and the modified VCARE do not raise different questions of safety and effectiveness. The modified VCARE is safe and effective and substantial equivalent to the predicate as demonstrated by non-clinical performance testing for the same intended use/ indications for use, target population, principles of operation, performance specifications, and standards for sterilization, packaging, and biocompatibility.

## I. Conclusion

The differences between the predicate and the modified design do not raise any new risks of safety or efficacy. Supporting information per this premarket submission confirms that the modified VCARE is safe and effective for its intended use and is substantially equivalent to the predicate device.