510(k) Summary of Safety and Effectiveness

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

This summary of 510(k) Safety and Effectiveness is being submitted in accordance with the requirements of 21 CR 807.92.

Submitter:

ConMed Corporatuion
525 French Road
Utica, NY 13502 USA

OCT 5 2007

Contact:

Brian Killoran
Manager, Regulatory Affairs
ConMed Corporation
525 French Road
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Date Prepared:

July 2, 2007

Name of Device:

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

Classification Name:

Cannula, Manipulator/Injector, Uterine

Device Classification:

Regulatory Class: Unclassified, but presumed to be Class II
PROCODE: LKF
Classification Panel: Obstetrics/Gynecology Panel
Regulation Number: Unknown

Predicate Device:

K955446	VCARE® (Vaginal-Cervical Ahluwalia's Retractor-Elevator) Retractor/Elevator	ConMed Corp.

Description of Device:

The CONMED VCARE® (Vaginal-Cervical Ahluwalia's Retractor-Elevator) Retractor/Elevator is a disposable, single-use device for manipulation of the uterus and cervix during surgical and diagnostic procedures. The device consists of a rigid, anatomically curved manipulator tube having at its proximal end an inflatable (intrauterine) balloon for insertion into the uterus to manipulate and maintain the proper attitude of the uterus during procedures such as hysteroscopy, Laparoscopic Assisted Vaginal Hysterectomy (LAVH), and Total Laparoscopic Hysterectomy (TLH). The intrauterine balloon is inflated by passing air from a syringe through a pilot balloon located at the distal end of the device and via a lumen internal to the manipulator (main) tube. Inflation is maintained by a one-way valve positioned in the pilot balloon. The pilot balloon also serves as

an indicator of intrauterine balloon inflation. **VCARE®** incorporates a system of cone-like components of which the forward or cervical cone surrounds and supports the cervix and the rear cone/flexible tube or vaginal cone is slid along the main tube to adjust the depth of balloon insertion and seal the vaginal cavity from within to maintain pneumoperitoneum and prevent abdominal deflation once the vagina is entered during laparoscopic procedures such as during a colpotomy. The rear cone/flexible tube component is secured at its proper depth with a locking mechanism situated at the rear of the flexible tube and external to the patient. At the rear of the device is a molded handle which allows the surgeon to manipulate the uterus to the position most desirable for the procedure being performed. At the extreme rear of the device is a standard male luer lock connection suitable for attachment of a standard syringe for injection of fluids or gases into the uterus through the main tube when diagnostic procedures are prescribed.

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 a colpotomy is performed.

Performance:

Performance of the ConMed VCARE® (Vaginal-Cervical Ahluwalia's Retractor-Elevator) Retractor/Elevator was tested and passed all functional and biocompatibility criteria.

Conclusion:

The ConMed VCARE® (Vaginal-Cervical Ahluwalia's Retractor-Elevator) Retractor/Elevator is substantially equivalent to the ConMed VCARE® Retractor/Elevator of 510(k) K955446.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 ' 2007

Mr. Brian Killoran
Manager, Regulatory Affairs
ConMed Corporation
525 French Road
UTICA NY 13502

Re: K071907
Trade Name: ConMed VCARE® Retractor/Elevator
Regulatory Class: Unclassified
Product Code: LKF
Dated: September 7, 2007
Received: September 10, 2007

Dear Mr. Killoran:

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, 1796, 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071907

Device Name: VCARE® (Vaginal-Cervical Ahluwalia's Retractor-Elevator) Retractor/Elevator

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071907