March 31, 2022

The O R Company Pty Ltd
Nicole Conway
Quality Assurance & Regulatory Affairs Manager
1/32 Silkwood Rise
Carrum Downs, Victoria 3201
Australia

Re: K220202
Trade/Device Name: Uterine ElevatOR PRO with OccludOR Balloon™
Regulation Number: 21 CFR§ 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF
Dated: January 28, 2022
Received: February 3, 2022

Dear Nicole Conway:

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 and Part 809); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K220202

Device Name
Uterine ElevatOR PRO with OccludOR Balloon ™

Indications for Use *(Describe)*
The Uterine ElevatOR PRO with OccludOR Balloon™ is indicated for manipulation of the uterus, and injection of fluids or gases during laparoscopic procedures including total laparoscopic hysterectomy, laparoscopic assisted vaginal hysterectomy, laparoscopic tubal occlusion, and diagnostic laparoscopy. The Uterine ElevatOR PRO with OccludOR Balloon™ maintains pneumoperitoneum during laparoscopic procedures 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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**Uterine ElevatOR PRO with OccludOR Balloon™ - 510(k) Summary**

## I. SUBMITTER

The O R Company Pty Ltd
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Phone: +61 3 9413 5555
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Contact Person: Nicole Conway
Email: nicole@theorcompany.com
Date Prepared: January 19, 2022

## II. DEVICE

Trade Name: Uterine ElevatOR PRO with OccludOR Balloon™
Model numbers: UE-OBPRO-32, UE-OBPRO-35, UE-OBPRO-37 and UE-OBPRO-40
Common Name: Uterine Manipulator / Injector
Regulation Number: 21 CFR 884.4530
Classification Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: II
Product Code: LKF

## III. PREDICATE DEVICE

Conmed Corporation, VCARE (Vaginal-Cervical Ahluwalia's Retractor-Elevator), K142716

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

**Reference devices:**
Coopersurgical, Inc., Koh Colpotomizer System, K954311

## IV. DEVICE DESCRIPTION

The Uterine ElevatOR PRO with OccludOR Balloon™ is a sterile, single-use medical device used to manipulate the uterus and cervix in surgical and diagnostic procedures. The device includes an insulated and anatomically designed stainless steel shaft with an intrauterine balloon and reference graduations (centimetres) at the proximal [to patient] end and an external handle at the distal end. The intrauterine balloon is inflated with air using a standard syringe (not included). The device has a vaginal cup that is pushed along the shaft to support a green cervical cup. The cervical cup provides a guide for colpotomy. There are four sizes of cervical cups available, 32mm, 35mm, 37mm, and 40mm, which correspond to the different model numbers. A locking assembly secures the position of the vaginal cup and therefore the cervical cup. Sites for suturing are located on the cervical cup. An Occluder Balloon further reduces

leakage of pneumoperitoneum during laparoscopic surgery. A port at the distal end of handle provides a channel for injection of fluids or gases.

## V. INDICATIONS FOR USE

The Uterine ElevatOR PRO with OccludOR Balloon™ is indicated for manipulation of the uterus, and injection of fluids or gases during laparoscopic procedures including total laparoscopic hysterectomy, laparoscopic assisted vaginal hysterectomy, laparoscopic tubal occlusion, and diagnostic laparoscopy. The Uterine ElevatOR PRO with OccludOR Balloon™ maintains pneumoperitoneum during laparoscopic procedures by sealing the vagina once colpotomy is performed.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

| **Attributes** | Uterine ElevatOR PRO with OccludOR Balloon K220202 | VCARE® Vaginal-Cervical-Ahluwalia's-Retractor-Elevator K142716 | Discussion |
|---|---|---|---|
| Manufacturer | The O R Company Pty Ltd | CONMED Corporation | --- |
| Class | II | II | Same |
| Regulation Number | 884.4530 | 884.4530 | Same |
| Regulation Generic Name | Cannula, Manipulator/Injector, Uterine | Cannula, Manipulator/Injector, Uterine | Same |
| Indications for Use | The Uterine ElevatOR PRO with OccludOR Balloon™is indicated for manipulation of the uterus, and injection of fluids or gasses during laparoscopic procedures including total laparoscopic hysterectomy, laparoscopic assisted vaginal hysterectomy, laparoscopic tubal occlusion, and diagnostic laparoscopy. The Uterine ElevatOR PRO with OccludOR Balloon™ maintains pneumoperitoneum during laparoscopic | 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. | Same |

| | | | |
|---|---|---|---|
| | procedures by sealing the vagina once colpotomy is performed. | | |
| Sterile | Yes, Ethylene Oxide | Yes, Ethylene Oxide | Same |
| Prescription Use | Yes | Yes | Same |
| Single Use | Yes | Yes | Same |
| Intrauterine Balloon inflation volume | 7 – 10 cc | 7 – 10 cc | Same |
| Intrauterine Balloon inflation method | The intrauterine balloon is inflated by passing air from a syringe through a pilot balloon located at the distal end of the device. 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. | The intrauterine balloon is inflated by passing air from a syringe through a pilot balloon located at the distal end of the device. 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. | Same |
| Occluder Balloon | Yes | No | Different |
| Mode of action | Mechanical device positioning prior to performing indicated laparoscopic procedures | Mechanical device positioning prior to performing indicated laparoscopic procedures | Same |
| Rigid, insulated and anatomically curved shaft | Yes | Yes | Same |
| Handle at the distal [to patient] end | Yes | Yes | Same |
| Intrauterine balloon at proximal end [to patient] end | Yes | Yes | Same |
| Intrauterine balloon material | PVC | PVC | Same |
| Device Components | **Direct patient contacting**:<br>Plug cap<br>Intrauterine Balloon<br>Intrauterine Balloon Colorant<br>Heat-shrink on the shaft<br>Stopper on the shaft<br>Graduation marking<br>Cervical cup<br>Vaginal Cup<br>Vaginal Cup Colorant | **Direct patient contacting**:<br>Intrauterine Balloon<br>Intrauterine Balloon Colorant<br>Heat-shrink on the shaft<br>Stopper on the shaft<br>Graduation marking<br>Cervical cup<br>Vaginal Cup<br>Vaginal Cup Colorant | Similar |

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| | | | |
|---|---|---|---|
| | OccludOR balloon<br>OccludOR balloon inflation line<br><br>**Non-contacting:**<br>Shaft<br>Thumbscrew & locking assembly<br>Thumbscrew & locking assembly colorant<br>Handle<br>Pilot balloon<br>Air inflation valve<br>Air Inflation line<br>Dye Injection port<br>Dye Injection port cap<br>Robert Clamp<br>Inflation port for OccludOR balloon | **Non-contacting**:<br>Shaft<br>Thumbscrew & locking assembly<br>Thumbscrew & locking assembly colorant<br>Handle<br>Pilot balloon<br>Air inflation valve<br>Air Inflation line<br>Dye Injection port<br>Dye Injection port cap | |
| Anatomical site | Mucosal Membranes- Uterus and Vagina | Mucosal Membranes- Uterus and Vagina | Same |
| Contact Period | Short-term contact (≤24 hours) | Short-term contact (≤24 hours) | Same |

Both the subject and predicate devices are sterile, single-use medical devices used to manipulate the uterus and cervix in surgical and diagnostic procedures. At a high level, the subject and predicate devices are based on the following same technological elements:

- An anatomically contoured shaft.
- An intrauterine balloon at the proximal [to patient] end, a handle at the distal end.
- A cervical cup and a vaginal cup.
- A locking mechanism to secure the vaginal cup in position.
- An inflation line for the intrauterine balloon.
- A dye injection port at the distal end of the handle.

The following technological differences exist between the subject and predicate devices:

- The subject device includes the OccludOR Balloon, which is similar to a feature of the Colpo-Pneumo Occluder device cleared under K954311.

These differences do not raise different questions of safety and effectiveness as compared to the predicate.

## VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

**Biocompatibility testing**

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1: 2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The subject device underwent the following tests:

- Cytotoxicity per ISO 10993-5:2009
- Irritation per ISO 10993-10:2010
- Sensitization per ISO 10993-5:2010
- Acute Systemic toxicity per ISO 10993-11:2017
- Pyrogenicity per ISO 10993-11 and USP <151>

The subject device is considered externally communicating device & surface contact device that may come in contact with tissue and breached or compromised surface respectively for a duration of less than 24 hours.

**Performance & mechanical testing**

The following performance and mechanical tests demonstrated that the subject device performs substantially equivalent to the predicate device:

- Intrauterine balloon integrity & concentric inspection
- Intrauterine balloon inflation stability test for a defined time period.
- Intrauterine balloon burst test
- Intrauterine balloon fatigue test
- Intrauterine balloon adhesion strength test
- OccludOR balloon outer diameter inspection & leakage free test
- OccludOR balloon deflation time test
- OccludOR balloon capacity test- reliability/safety
- OccludOR balloon fatigue durability test
- OccludOR balloon burst test
- Vaginal cup air leakage test
- Cervical cup temperature test
- Air inflation valve test
- Dye-injection port compliance & leakage test
- Thumb screw strength test
- Locking force test of vaginal cup
- Ease of movement of vaginal cup along the shaft
- Cervical cup detachment force test
- Cervical cup stopper adhesion strength test

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- Device tensile strength
- Handle joint strength
- Tip deflection
- Ultrasonic welding strength

In all testing, the subject device met the pre-specified acceptance criteria.

**Conclusion:**
The intended use of the subject device is identical to the predicate device. The subject device has similar technological characteristics to the predicate device. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. All testing undertaken to demonstrate substantial equivalence of the subject device meet the predetermined acceptance criteria. The test results demonstrate that the subject device is as safe and effective as the predicate device.

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