DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 7, 2017

ClearPath Surgical, Inc.
Puja Ohlhaver
CEO
1052 High Street
Palo Alto, CA 94301

Re: K163214
Trade/Device Name: Unicare System & Unicare Manipulator
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKF
Dated: November 14, 2016
Received: November 16, 2016

Dear Puja Ohlhaver:

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,

Joyce M. Whang -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)*

K163214

Device Name

Unicare System & Unicare Manipulator

Indications for Use *(Describe)*

The Unicare System is indicated for manipulation of the uterus and injection of fluids 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 during a colpotomy.

The Unicare Manipulator is indicated for manipulation of the uterus and injection of fluids during laparoscopic procedures, such as minilap, laparoscopic tubal occlusion, or diagnostic laparoscopy.

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.

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510(k) SUMMARY

Date Prepared:	January 30, 2017
Submitter:	ClearPath Surgical, Inc. 1052 High St. Palo Alto, CA 94301 Telephone: 1 (888) 979-7467 ext. 700 Fax: 1 (888) 979-6685
Contact:	Puja Ohlhaver CEO puja@clearpathsurgical.com Telephone: 1 (888) 979-7467 ext. 700 Fax: 1 (888) 979-6685
Classification:	Unclassified
Product Code:	LKF
Product Code Name:	Cannula, Manipulator/Injector, Uterine
Trade/Proprietary Name of Device:	Unicare System™ and Unicare Manipulator™
Common Name:	Uterine Manipulator
Legally Marketed Predicate Device:	VCARE manufactured by Conmed Corporation, K071907 (Oct. 5, 2007), Product code LKF
Predicate Device Design-related Recalls:	There are no design related recalls associated with the predicate device.

Description of the new Unicare System™ and Unicare Manipulator™:

The new Unicare System™ is a sterile, disposable, single-use device for manipulation of the uterus and cervix during surgical and diagnostic procedures. The Unicare System™ consists of the Unicare Manipulator™, a rear Stabilizer™, and a set of interchangeable, forward Collars™.

The Unicare Manipulator™ is a rigid, anatomically curved cannula having at its proximal end a tip for insertion into the uterus to manipulate and maintain the proper attitude of the uterus. The Unicare Manipulator incorporates a sliding tube component with a proximal ball that provides a positive stop from

over-penetration of the uterine cavity and counter traction with the tip for manipulation. At the distal end of the device is a handle which allows the surgeon to manipulate the uterus to the position most desirable for the procedure being performed. At the extreme distal end of the device is a standard luer port suitable for attachment of a standard syringe for injection of fluids or gases into the uterus through the cannula.

The Unicare System also incorporates a set of interchangeable, forward Collars™ and a rear Stabilizer™. The appropriately sized Collar surrounds the cervix, delineates the fornix, and supports and defines the vaginal wall. The rear Stabilizer and a sliding tube are slid along the cannula to adjust the depth of tip 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 Stabilizer and sliding tube components are secured at their proper depth with a locking mechanism situated distal to the sliding tube and external to the patient.

The Unicare Manipulator™ will be offered and sold separately from the Unicare System™. The Unicare Manipulator™ does not include a rear Stabilizer™ or a set of interchangeable, forward Collars™, and is therefore indicated only for a subset of procedures of the Unicare System™.

Table 1.1 lists the key components and their respective materials. The new Unicare System™ and Unicare Manipulator™ have limited surface contact of less than or equal to 24 hours as categorized per ISO 10993-1:2009.

UNICARE SYSTEM & UNICARE MANIPULATOR	Materials	Direct Patient Contact
Cannula	Steel	Yes
Tip	Polymer	Yes
Cannula Insulation (i.e. Heat Shrink Tubing)	Polymer	Yes
Handle	Polymer	No
Lock Body	Polymer	Yes
Thumbscrew	Polymer	Yes
Cap	Polymer	No
Sliding Tube	Polymer	Yes
Luer Port	Polymer	No
String*	Suture	Yes
Collars*	Polymer	Yes
Stabilizer *	Polymer	Yes
Retrieval Ring*	Polymer	Yes

Table 1.1 – List of Materials

(indicates components of Unicare System only)*

Indications for Use:

The Unicare System™ is indicated for manipulation of the uterus and injection of fluids 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 during a colpotomy.

The Unicare Manipulator™ is indicated for manipulation of the uterus and injection of fluids during laparoscopic procedures, such as minilap, laparoscopic tubal occlusion, or diagnostic laparoscopy.

Comparison of the Technological Features to the Predicate Device:

The new Unicare System™ and Unicare Manipulator™ are substantially equivalent to the predicate ConMed VCARE Retractor/Elevator (K071907). The new and predicate devices are very similar in overall design and technology, principles of operation, and intended use.

The main differences between the new Unicare System™ and Unicare Manipulator™ and the predicate VCARE Retractor/Elevator (K071907) device are the following:

1. The new Unicare System™ and Unicare Manipulator™ utilize a bulbous-shaped tip instead of the predicate device's inflatable balloon tip.

2. The new Unicare System™ includes a rear Stabilizer and a set of forward interchangeable Collars, whereas the predicate VCARE includes a rear cup and a fixed forward cup.

3. The new Unicare System™ includes a Retrieval Ring and String attached to the forward Collar to facilitate retrieval of the Collar, whereas the predicate device's forward cup lacks a Retrieval Ring and String.

4. The new Unicare System™ secures the cervix with a suture applied on the rear Stabilizer, whereas the predicate device secures the cervix with a suture applied on the forward cup.

The differences between the new Unicare System™ and Unicare Manipulator™ and the predicate ConMed VCARE (K071907) device do not raise different questions of safety of effectiveness.

Table 1.2 below shows selected properties and characteristics of the new Unicare System™ and Unicare Manipulator™ and the predicate ConMed VCARE (K071907) device.

Device Comparison Table 1.2

Descriptive Information	Results: NEW UNICARE SYSTEM & UNICARE MANIPULATOR	Results: PREDICATE DEVICE: ConMed VCARE (K071907)	Substantial Equivalence
Indications for Use	The UNICARE SYSTEM is indicated for manipulation of the uterus and injection of fluids 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 during a colpotomy. The UNICARE MANIPULATOR is indicated for manipulation of the uterus and injection of fluids during laparoscopic procedures, such as minilap, laparoscopic tubal occlusion, or diagnostic laparoscopy.	The 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.	Similar. The Unicare System's indications are nearly identical to VCARE's indications. The Unicare System is indicated for "injection of fluids" whereas VCARE is indicated for "injection of fluids or gases." Unicare "maintains pneumoperitoneum during a colpotomy," whereas VCARE "maintains pneumoperitoneum by sealing the vagina once a colpotomy is performed." These differences do not change the Unicare System's intended use. Similar, the Unicare Manipulator's indications are a subset of the Unicare System's indications and are therefore included within the predicate VCARE's indications.

Product Code	LKF	LKF	Same
Intended Users	Medical Professionals	Medical Professionals	Same
Environment of Use	Clinical Setting	Clinical Setting	Same
Single-Use	Yes	Yes	Same
Sterile	Yes (Ethylene Oxide)	Yes (Radiation)	Similar – both products are sterile
Materials	**Materials for NEW UNICARE SYSTEM & UNICARE MANIPULATOR**	**Materials for PREDICATE DEVICE: ConMed VCARE (K071907)**	**Substantial Equivalence**
Cannula	stainless steel	stainless steel	Same
Tip	hard thermoplastic	synthetic plastic polymer	Similar – both products are made of polymers.
Collars	hard thermoplastic	hard thermoplastic	Similar – both products are made of polymers.
Stabilizer	hard thermoplastic	flexible thermoplastic	Similar – both products are made of polymers.
Retrieval Ring	hard thermoplastic	N/A	No new question of safety and effectiveness
Cannula Insulation (i.e. Heat Shrink Tubing)	polymer	polymer	Similar – both products are made of polymers.
Handle	hard thermoplastic	hard thermoplastic	Similar – both products are made of polymers.
Lock Body	hard thermoplastic	hard thermoplastic	Similar – both products are made of polymers.

Thumbscrew	hard thermoplastic	hard thermoplastic	Similar – both products are made of polymers.
Cap	hard thermoplastic	hard thermoplastic	Similar – both products are made of polymers.
String	suture	N/A	No new question of safety and effectiveness
Sliding Tube	flexible thermoplastic	flexible thermoplastic	Similar – both products are made of polymers.
Luer Port	hard thermoplastic	hard thermoplastic	Similar – both products are made of polymers.
Luer Fitting	hard thermoplastic	hard thermoplastic	Similar – both products are made of polymers.
Ink	ink	ink	Similar – both are inks.
Features	**NEW UNICARE SYSTEM & UNICARE MANIPULATOR**	**PREDICATE DEVICE: ConMed VCARE (K071907)**	**Substantial Equivalence**
Electrically insulated Cannula	yes	yes	Same
Hollow Cannula	yes	yes	Same
Distal Cannula Curvature	yes	yes	Same
Graduation marks measuring distance from most proximal point on tip	yes	yes	Same

Bulbous tip	yes (Rigid)	yes (Inflatable)	Similar – No different questions of safety and effectiveness
Tip enables direct introduction of dye/contrast media via the Luer Port	yes	yes	Same
Standard Luer Port suitable for attachment of a standard syringe	yes	yes	Same
Continuous flow between Luer Port and Tip	yes	yes	Same
Cap to seal Luer Port	yes	yes	Same
Sliding Tube that slides along the Cannula	yes	yes	Same

Lock Body	yes	yes	Same
Thumbscrew	yes	yes	Same
Rear Stabilizer	yes (System only)	yes, rear cup	Similar - No different questions of safety and effectiveness
Forward Collar	yes (System only)	yes, forward cup	Similar - No different questions of safety and effectiveness
Double rim on forward Collar	yes (System only)	yes, on forward cup	Same
Multiple size forward Collars	yes, interchangeable Collars on single device (System only)	yes, multiple devices	Similar - No different questions of safety and effectiveness
Holes to allow securing the cervix with a suture	yes, the rear Stabilizer includes suture holes (System only)	yes, the forward cup includes suture holes	Similar - No different questions of safety and effectiveness
Collars to support the cervix	yes, interchangeable forward Collars (System only)	yes, fixed forward cup	Similar – No different questions of safety and effectiveness

In conclusion, the differences in technological characteristics identified in the table above do not raise different questions of safety and effectiveness.

Testing:

Differences in technological characteristics were evaluated through performance testing.

Biocompatibility:

Biocompatibility of the subject devices was tested per ISO 10993-1 (2009/(R)2013) Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, and they included:

- Cytotoxicity: ISO 10993-5 (2009/(R)2014) Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Sensitivity: ISO 10993-10 (2010/(R)2014) Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Irritability: ISO 10993-10 (2010/(R)2014) Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Systemic Toxicity: ISO 10993-11 (2006) Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity

The Unicare System™ and Unicare Manipulator™ were found to be non-cytotoxic, non-irritating, non-sensitizing, and not acutely toxic.

Non-Clinical Performance Testing:

Non-clinical product testing of the new Unicare System™ and Unicare Manipulator™ was completed and met all of the acceptance criteria. Testing included the following:

- Mechanical: the device was evaluated for mechanical performance including flow rates, strength and applied clinical forces.
- Packaging: the device packaging was evaluated for structural integrity and maintenance of the sterile barrier after transit per ASTM F1886/F1886M-09:2013 (Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection), ASTM F2096-11:2011 (Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization), and ASTM F88/F88M-15:2015 (Seal Strength).
- Sterility: the device was evaluated for sterility per ISO 11137-1:2013 (Sterilization of health care products – Radiation – Part 1: Requirements for Development Validation and routine control of a sterilization process

for medical devices) and ISO 11137-2:2013 (Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose) .

- Accelerated aging: the device was evaluated for non-clinical performance after aging. ASTM F1980-07:2011 (Guide for Accelerated Aging of Sterile. Medical Device Packages).

The acceptance criteria were met for all non-clinical performance testing of the new Unicare System™ and Unicare Manipulator™. The results demonstrate the subject devices are as safe and effective as the predicate.

Clinical Performance Testing:

No clinical testing has been performed in support of this Unicare System™ and Unicare Manipulator™ 510(k) submission.

Conclusion of Substantial Equivalence:

The indications for use and basic technological characteristics of the Unicare System™ and Unicare Manipulator™ are similar to those of the predicate. Minor differences in the indications for use of the Unicare System™ and Unicare Manipulator™ do not alter the intended use from that of the predicate. Differences in technological characteristics between the subject devices and the predicate do not raise different questions of safety and effectiveness. The performance testing provided support that the subject devices are as safe and effective as the predicate. Therefore, the Unicare System™ and Unicare Manipulator™ are substantially equivalent to the predicate.