UC-CARE
Medical Systems

510(K) SUMMARY

UC-CARE Positioning System

510(k) Number K 082919

OCT 2 7 2008

Applicant's Name: UC-CARE, Ltd.
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Trade Name: **UC-CARE Positioning System (UCP System)**

Classification:
Name: Urological Catheter and Accessories
Product Code: EZL
Regulation No: CFR 21 876.5130
Class: II
Panel: Urological Catheter and Accessories

Device Description: The UCP System is a positioning device used to outline the urethral course during diagnostic or therapeutic transperineal ultrasound-guided prostate procedures.

The UCP System combines the function of a positioning and imaging-visibility enhancing device with the configuration of a urological Foley catheter. The configuration and material composition of the patient contact portion of the UCP System part are identical to a commercially available (FDA cleared) urological catheter including a balloon retention mechanism. The device is

comprised of two main components: the **Urethral Catheter** and the **Catheter Holder**. The device is used together with any commercial endorectal ultrasound stepper and stabilizer as well as a brachy-like template grid, available in the market for transperineal prostate biopsy, brachytherapy, or cryotherapy. The use of the device facilitates simple and safe transperineal needle insertion for diagnostic and therapeutic prostate procedures.
The UCP System's Catheter is introduced into the urethra as a sterile urological catheter and is retained in place by inflating the balloon tip and by the Catheter Holder, which is mounted over the ultrasound stepper and stabilizer.

Intended Use Statement:

The UC-CARE Positioning System is a mechanical positioning device, introduced into the urethra as a sterile urological catheter for visualizing the urethral course, aimed for assistance in diagnostic or therapeutic endorectal ultrasound-guided prostate procedures.

The device is retained in place by inflating the balloon tip and by attaching it over an ultrasound-stepper and stabilizer with a Brachy-like template.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of approval
BeamCath	K042110	25 Feb, 2005
Disposable Endocavity Ultrasound needle/Biopsy Guide	K970514	20 Jun, 1997
Simplastic™ Catheter	K963993	17 Dec, 1996

Conclusion:

UC-CARE Ltd. believes that, based on the information provided in this submission, the UCP System is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2008

UC-CARE Medical Systems Ltd.
% Mr. Jonathan S. Kahan
Regulatory Counsel
Hogan & Hartson, LLP
Columbia Square, 555 Thirteenth Street, N.W.
WASHINGTON DC 20004

Re: K082919
Trade/Device Name: UC-CARE Positioning System
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: September 30, 2008
Received: September 30, 2008

Dear Mr. Kahan:

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.

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(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 Biometrics' (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,

Joyce M. Whang

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

UC-CARE
Medical Systems

K082919

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082919

Device Name: UC-CARE Positioning System

Indications for Use:

The UC-CARE Positioning System is a mechanical positioning device, introduced into the urethra as a sterile urological catheter for visualizing the urethral course, aimed for assistance in diagnostic or therapeutic endorectal ultrasound-guided prostate procedures.

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 General & Plastic Surgery Devices
510(k) Number

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082919