K063611

UTAH MEDICAL PRODUCTS INC.

MAY 23 2007

SECTION 9: 510(k) SUMMARY

510(k) Owner:	Utah Medical Products, Inc.
Address:	7043 South 300 West Midvale, UT 84047 USA
Telephone No.:	(801) 566-1200
Fax No.:	(801) 566-2062
Contact:	Kevin L. Cornwell, CEO
Date:	9 April 2007
Trade Name:	TVUS/HSG-Cath™ Saline/ Contrast Media Infusion Catheter
Common Name:	Hysterosonography or Hysterosalpingography Catheter
Classification:	Obstetric-gynecologic specialized manual instrument, 21 CFR 884.1700 (a)(4)
Predicate Device:	H/S Elliptosphere Catheter, (K013972) ACKRAD Laboratories, Inc., a CooperSurgical company.
Intended Use:	TVUS/HSG-Cath™ is intended for intracervical injection of saline into the uterus for enhanced transvaginal ultrasonography (TVUS), also known as saline infusion sonography (SIS). TVUS/HSG-Cath may also be used for the delivery of contrast media into the female reproductive tract for diagnostic examination of the uterus and fallopian tubes.
Indications for Use:	TVUS (SIS) with saline infusion: • persistent abnormal or dysfunctional uterine bleeding • suspected myometrial or intraluminal abnormalities (e.g., fibroids or polyps) • thickened or irregular endometrium • recurrent pregnancy loss • pre- and post-operative assessment of uterine pathology HSG with contrast media: • unexplained infertility • recurrent pregnancy loss

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Kevin Cornwell
Chairman & CEO
Utah Medical Products, Inc. (UTMD)
7043 South 300 West
MIDVALE UT 84047

MAY 23 2007

Re: K063611
Trade/Device Name: TVUS/HSG-Cath™; Saline/Contrast Media Infusion Catheter
Regulation Number: None
Regulation Name: Unclassified
Regulatory Class: II
Product Code: 85 LKF
Dated: April 13, 2007
Received: April 16, 2007

Dear Mr. Cornwell:

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 (Premarket Approval), 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.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" (21 CFR 807.97). 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 (301) 443-6597 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

SECTION 3: INTENDED USE / INDICATIONS for USE

510(k) Number: K063611

Device Name: TVUS/HSG-Cath™; Saline/ Contrast Media Infusion Catheter

Intended Use: TVUS/HSG-Cath™ is intended for intracervical injection of saline into the uterus for enhanced transvaginal ultrasonography (TVUS), also known as saline infusion sonography (SIS). TVUS/HSG-Cath may also be used for the delivery of contrast media into the female reproductive tract for diagnostic examination of the uterus and fallopian tubes.

(The intended use is the same as the intended use of the predicate devices listed in Section 8, Substantial Equivalence.)

Indications for Use: TVUS (SIS) with saline infusion:

- persistent abnormal or dysfunctional uterine bleeding
- suspected myometrial or intraluminal abnormalities (e.g., fibroids or polyps)
- thickened or irregular endometrium
- recurrent pregnancy loss
- pre- and post-operative assessment of uterine pathology

HSG with contrast media:

- unexplained infertility
- recurrent pregnancy loss

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-the-Counter Use
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063611