UTAH MEDICAL PRODUCTS INC.

JAN 1 1 2011

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:	3 January 2011
Trade Name:	BT-Cath
Common Name:	Intrauterine Balloon Tamponade Catheter
Classification:	Obstetric-gynecologic specialized manual instrument, 21 CFR 884.4530; Product Code OQY
Predicate Devices:	Bakri Uterine Balloon Tamponade, (K013597, K062438) Cook Ob/Gyn
Indications for Use:	BT-Cath is intended to provide temporary control or reduction of uterine bleeding during postpartum hemorrhage that is unresponsive to standard conservative therapy including uterine massage and oxytocin administration.

Device Description:	The BT-Cath consists of an extruded silicone dual lumen catheter with an inflatable molded silicone tamponade balloon attached on the distal end. One lumen of the catheter serves as the conduit through which saline is infused into the balloon after insertion into the bleeding uterus. When inflated properly to press against the uterine wall, the balloon provides compression against multiple sites of torn arteries, ruptured sinuses, lacerations and other tissue evoking hemorrhage. The second lumen, which is open at the distal end of the catheter, provides a drainage port for blood and other bodily fluids. At the proximal end of the catheter, a stopcock retains the saline in the balloon until a clinician gradually drains it allowing the uterus to contract. For ease of filling the balloon with multiple syringes, a check valve is also provided at the proximal end. The device is latex-free and provided sterile.
Comparison to predicate devices:	There are insignificant differences in the physical dimensions and physical configuration of the balloon tamponade catheters. The technological characteristics, methods of use, materials, intended use, indications for use and contraindications are the same as the predicate devices. Biocompatibility and shelf-life testing were also assessed to demonstrate substantial equivalence.
Performance Data:	Substantial equivalence is also based on an assessment of mechanical tests where the structural integrity of the balloon, including the relationship of volume of saline infused into the balloon and resulting balloon diameter, the burst volume of the balloon, and the ability of the balloon to hold its shape and not leak during repeated and prolonged inflations; the structural integrity of the catheter using leak tests; and the tensile strength in each joint in the devices were evaluated. Both the BT-Cath and the Bakri device were tested and found to achieve structural integrity with a reasonable safety factor. Clinical feedback was obtained after about 840 uses of BT-Cath by U.S. clinicians that indicates the device consistently achieved its intended purpose without any reported likelihood of patient injury.

K. Cornwell

Kevin L. Cornwell
Chairman & CEO
Utah Medical Products, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

JAN 11 2011

Re: K101535
Trade Name: BT-Cath®
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: OQY
Dated: January 3, 2011
Received: January 3, 2011

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. 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.

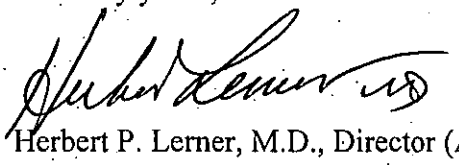
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3: INTENDED USE / INDICATIONS for USE

JAN 1 1 2011

510(k) Number: **K101535**

Device Name: UTMD BT-Cath - Balloon Tamponade Catheter for Postpartum Uterine Hemorrhage (BTC-100)

Indications for Use:

BT-Cath (BTC-100) is intended to provide temporary control or reduction of uterine bleeding during postpartum hemorrhage that is unresponsive to standard therapy including massage and oxytocin administration.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101535