



Food and Drug Administration
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March 25, 2015

Clinical Innovations, LLC
Tom Haueter
Director, Quality and Regulatory Affairs
747 West 4170 South
Murray, UT 84123

Re: K150573

Trade/Device Name: ebb Complete Tamponade System
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: OQY
Dated: March 6, 2015
Received: March 6, 2015

Dear Tom Haueter,

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 yours,

Benjamin R. Fisher -S

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

Indications for Use

510(k) Number (if known)

K150573

Device Name

ebb Complete Tamponade System

Indications for Use (Describe)

The ebb Complete Tamponade System is indicated for use in providing temporary control or reduction of postpartum uterine bleeding. Inflation of the Vaginal Balloon anchors the Uterine Balloon and provides vaginal tamponade if vaginal bleeding is present. The ebb Complete Tamponade System should only be used in the setting of post-partum uterine bleeding when conservative management is warranted.

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

Clinical Innovations' ebb Complete Tamponade System

Clinical Innovations, LLC

747 W. 4170 S.
Murray, UT 84123

Phone: 801-260-6100
Fax: 801-266-7373

Contact Person: Tom Haueter
Date Prepared: March 3, 2015
Name of Device: ebb Complete Tamponade System
Common or Usual Name: Intrauterine tamponade balloon
Classification Name: Class II per 21 CFR 884.4530
Product Code: OQY

Predicate Device

K091958 Belfort-Dildy Obstetric Tamponade System

Purpose of the Special 510(k) notice.

The ebb Complete Tamponade System is a modification to the Belfort-Dildy Obstetric Tamponade System (K091958). Clinical Innovations has modified the subject device and have completed verification and validation testing to verify that the modified device is substantially equivalent to the predicate. Specifically, the company has minimized the potential for leaks at the distal end of the uterine balloon by modifying the bond at the distal end of the uterine balloon from a heat bond to a UV bond.

Indications for Use

The ebb Complete Tamponade System is indicated for use in providing temporary control or reduction of postpartum uterine bleeding. Inflation of the Vaginal Balloon anchors the Uterine Balloon and provides vaginal tamponade if vaginal bleeding is present. The ebb Complete Tamponade System should only be used in the setting of post-partum uterine bleeding when conservative management is warranted.

Technological Characteristics

The ebb Complete Tamponade System and the predicate have the same technological characteristics. Both devices are disposable, multiple lumen catheters attached to an inflatable balloon system designed to provide tamponade for controlling hemorrhage from the uterus and vagina. The devices consist of two inflatable balloons: The upper uterine balloon is inflated inside the uterus and the lower vaginal balloon is inflated inside the vagina. Inflation is accomplished with isotonic intravenous fluid such as normal saline or Ringers Lactate. The uterine balloon catheter has

separate lumens to enable inflation/deflation, irrigation and drainage. The vaginal balloon catheter has a lumen to enable inflation/deflation. The uterine and vaginal balloons are permanently assembled and are not to be separated. The devices may be retained in position for up to 24 hours in the post-operative mode of treatment, and are supplied sterile in peel open pouches for one time use to a single patient. There are no differences in the material, chemical composition or energy source of the subject and predicate devices. The change in design of the subject device is limited to the modification to the bond of the distal end of the uterine balloon from a heat bond to a UV bond, to increase the bond strength.

Performance Data

Testing performed on the modified devices demonstrated significant improvement in strength over the previous version. The testing consisted of subjecting the device to physiologic pressures under worst-case conditions. None of the modified devices failed under those conditions. Further, we subjected the modified devices to 7.5 times the pressure indicated in the published literature, and no failures were encountered.

Substantial Equivalence

The ebb Complete Tamponade System has the same intended use and similar indications, principles of operation, and technological characteristics as the Belfort-Dildy Obstetric Tamponade System. The minor differences between the subject and the predicate devices do not raise any new questions of safety or effectiveness. Performance data demonstrates that the ebb Complete Tamponade System is as safe and effective as the Belfort-Dilty Obstetric Tamponade System. Thus, the ebb Complete Tamponade System is substantially equivalent to its predicate device.

