DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 14, 2016

Clinical Innovations, LLC
Tom Haueter
Director, QA/RA
747 West 4170 South
Murray, UT 84123

Re: K153591
Trade/Device Name: ebb Complete Tamponade System
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-Gynecologic Specialized Manual Instrument
Regulatory Class: Class II
Product Code: OQY
Dated: December 14, 2015
Received: December 16, 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,

Herbert P. Lerner -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)*
K153591

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: December 14, 2015

Name of Device and Name/Address of Sponsor

ebb Complete Tamponade System

Clinical Innovations, LLC

747 W. 4170 S.

Murray, UT 84123

Common or Usual Name: Intrauterine tamponade balloon

Classification Name: Class II per 21 CFR 884.4530

Product Code: OQY

Predicate Device:

K150573 ebb Complete Tamponade System

Purpose of the Special 510(k) notice:

The subject ebb Complete Tamponade System is a modification to the previous ebb Complete Tamponade System (K150573)**.** This modification is the addition of a UV Band around the proximal and distal ends of the vaginal and uterine balloons.

Device Description:

The ebb Complete Tamponade System is a disposable, multiple lumen catheter attached to an inflatable balloon system designed to provide tamponade for controlling hemorrhage from the uterus and vagina. The device consists 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 device may be retained in position for up to 24 hours in the post-operative mode of treatment. The ebb Complete Tamponade System is supplied sterile in peel open pouches for one time use to a single patient.

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:

	Ebb Complete Tamponade System Device	**Ebb Complete Tamponade System (K150573)**	**Comparison**
Intended Use /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.	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.	Same
Technology	Tamponade achieved by inflation of balloon with saline solution	Tamponade achieved by inflation of balloon with saline solution	Same
Operating Principle	Manual Operation	Manual Operation	Same

Components	- Uterine balloon to create tamponade, recommended fill volume of 750 ml - Vaginal balloon to assist in positioning, recommended fill volume of 350 ml - Spike assembly to allow for rapid fluid fill from IV bag - Leuer assembly for a measured fill - Drainage lumen - Separate irrigation lumen	- Uterine balloon to create tamponade, recommended fill volume of 750 ml - Vaginal balloon to assist in positioning, recommended fill volume of 350 ml - Spike assembly to allow for rapid fluid fill from IV bag - Leuer assembly for a measured fill - Drainage lumen - Separate irrigation lumen	Same
Safety Features	Labels on Lumens for immediate identification	Labels on Lumens for immediate identification	Same
Sterility	Ethylene Oxide, SAL of 10^{-6}	Ethylene Oxide, SAL of 10^{-6}	Same
Reuse	Single Use	Single Use	Same
Shelf Life	3 Years	3 Years	Same
Dimensions	- Recommended uterine balloon fill volume of 750 ml - Recommended vaginal balloon fill volume of 350 ml	- Recommended uterine balloon fill volume of 750 ml - Recommended vaginal balloon fill volume of 350 ml	Same

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 cyclic physiologic pressures under more challenging conditions than indicated in published literature. None of the modified devices failed under those conditions.

Substantial Equivalence

The ebb Complete Tamponade System has the same intended use and similar indications, principles of operation, and technological characteristics as the previous ebb Complete Tamponade System. The minor differences is the addition of a UV Rings at the distal end and proximal ends of the uterine and vaginal balloons, does 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 ebb Complete Tamponade System. Thus, the ebb Complete Tamponade System is substantially equivalent to its predicate device.