K093508

MAR - 4 2010

## 5. 510(k) Summary

**Submitters Name**: Doranne Frano
**Address**: WomanCare Global
300 Market Street Suite 134
Chapel Hill, NC 27516
**Phone Number**: 919 442-2621
**Contact Person**: Susanne Parks
**Date Summary Prepared**: November 6, 2009

**Device Name:** Rigid Uterine Cannulae
**Common** Name: Uterine Cannulae
**Classification Name**: Vacuum Abortion System, Regulation Number (884.5070)
Product Code: Cannulae Suction Uterine (HGH), Class II device

**Establishment Registration Number**: 3008007615

**Identification of Substantially Equivalent Device**: Berkeley VC10-Vacuum Curettage System and Accessories (K030935) and Synevac Vacuum Curettage System 10 (K813282). These 510(k) applications include vacuum pumps as well as the uterine suction cannulae and accessories.

**Description of Device**: The Rigid Cannulae are injection molded plastic devices approximately 190mm in length, made from a styrenic copolymer manufactured in sizes 6mm, 7mm, 8mm, 9mm, 10mm, 11mm, and 12mm (outer diameter), straight and curved.

**Intended Use**: For uterine aspiration/uterine evacuation in obstetric and gynecologic patients. Indications for use are rapid transcervical aspiration of the uterine cavity during the first trimester of pregnancy.

**Comparison to Predicate:** The Rigid Cannulae and the predicate device are both plastic injection molded devices. They share the same design. They both have a single scoop end and similar dimensional features. The raw materials used to produce the parts are similar. Both are attached to a vacuum source to perform uterine aspiration procedures. Bench Testing was performed to compare the physical strength of the materials (three point bend and compression testing) as well as vacuum testing (integrity and performance).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAR - 4 2010

Ms. Susanne Parks
Director Regulatory and Logistics
WomanCare Global
300 Market Street, Suite 134
CHAPEL HILL NC 27516

Re: K093508
Trade/Device Name: Rigid Uterine Cannulae, Curved and Straight
Regulation Number: 21 CFR §884.5070
Regulation Name: Vacuum abortion system
Regulatory Class: II
Product Code: HGH
Dated: February 1, 2010
Received: February 3, 2010

Dear Ms. Parks:

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K093508

## 4. Indications for Use Statement

**Device Name:** Rigid Uterine Cannulae

**Indications for Use:** For rapid transcervical aspiration of the uterine cavity during the first trimester of pregnancy.

Prescription Use__X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line-continue on another page if needed)

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Concurrence of CDRH, Office of Devie Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093508