K112165

MAY 2 4 2012

510(k) Summary

Date Submission Prepared: July 26, 2011
Revision B Prepared: May 16, 2012

Submitter:

Apex Medical Technologies, Inc.
10064 Mesa Ridge Court, Suite 202
San Diego, CA 92121
USA
Phone: (858) 535-0012
Fax: (858) 535-9715
Establishment Registration Number 2025773

Contact: Scott Herrick
Title: Senior Development Engineer

New Device:

Trade Name:	Rhea Cup
Common Name:	Menstrual cup
Classification Name:	Cup, Menstrual
Review Panel:	Obstetrics/Gynecology
Product Code:	HHE
Regulation Number:	21 CFR 884.5400
Device Class:	II

Predicate Devices:

Trade Name:	Tassaway	Trade Name:	BelleCup
510(k) number:	K803250	510(k) number:	K092985
Product Code:	HHE	Product Code:	HHE
Trade Name:	Lunette		
510(k) number:	K091754		
Product Code:	HHE		

Device Description:

The Rhea Cup is a reusable menstrual cup placed in the vagina to collect blood and cervical debris that is extruded from the uterus via the cervix during menstruation. The Rhea Cup will be made in two model sizes to allow for the variability of the female vagina and menstrual flow due to normal differences between women as well as the effects of childbirth. Model 1 holds approximately 25ml of fluid and is for women who have never given birth vaginally. Model 2 holds approximately 30ml of fluid and is for women who have given birth vaginally.

The Rhea Cup is made of a flexible silicone elastomer which allows for easy insertion and a comfortable fit in the body. This material is durable and allows the cup to be used during many menstrual cycles. The Rhea Cup is comprised of a body, which acts as a receptacle for fluid and a ribbed tail attached at the base of the body, providing support when removing the cup from the vagina.

The Rhea Cup is made of a silicone elastomer, which has been cleared by the FDA for use in the BelleCup (K092985) predicate device.

No applicable mandatory performance standards or special controls exist for this device.

The Rhea Cup is not supplied sterile.

Intended Use:

The Rhea Cup is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation.

Comparison to Predicate Device:

The Rhea Cup and BelleCup menstrual cups are both made of the same silicone elastomer, LIM 6040-D2 and the two devices are substantially equivalent in material, technological characteristics and intended use.

The Rhea Cup is substantially equivalent to the Lunette menstrual cup in dimensions, technological characteristics and intended use. The lunette is made from a similar silicone elastomer material.

The Rhea Cup has the same intended use and similar characteristics as all of the predicate devices including methods for insertion and removal, fluid holding capacity and wear time.

Any differences between the Rhea Cup and the predicate devices do not affect the intended use or alter the technology of the device. No new questions of safety or effectiveness are raised by differences in technology or materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Scott Herrick
Senior Development Engineer
Apex Medical Technologies, Inc.
10064 Mesa Ridge Court, Suite #202
SAN DIEGO CA 92121

MAY 24 2012

Re: K112165
Trade/Device Name: Rhea Cup
Regulation Number: 21 CFR§ 884.5400
Regulation Name: Menstrual cup
Regulatory Class: II
Product Code: HHE
Dated: May 16, 2012
Received: May 17, 2012

Dear Mr. Herrick:

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,

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): K112165

Device Name: Rhea Cup

Indications for Use:

The Rhea Cup is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112165