510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMVDA 1990 and 21 CFR §807.92.

510(k) number:

1. Submitter's Identification:

JUN 28 2010

Librette, Inc.
9540 Bobby McLamb Dr
Linden, NC 28356
USA
Submitter Phone: 910- 892-7154
Submitter Fax: 877- 248-9191
Submitter Contact: Carissa Ulvestad
Title: Owner
Date Summary Prepared: June 25, 2010

2. Name of the Device:
BelleCup

3. Predicate Device Information:
MoonCup
510(k) Number: K040335
MoonCup LLC.
One E. Main St.
Madision, WI 53701

4. Device Description:

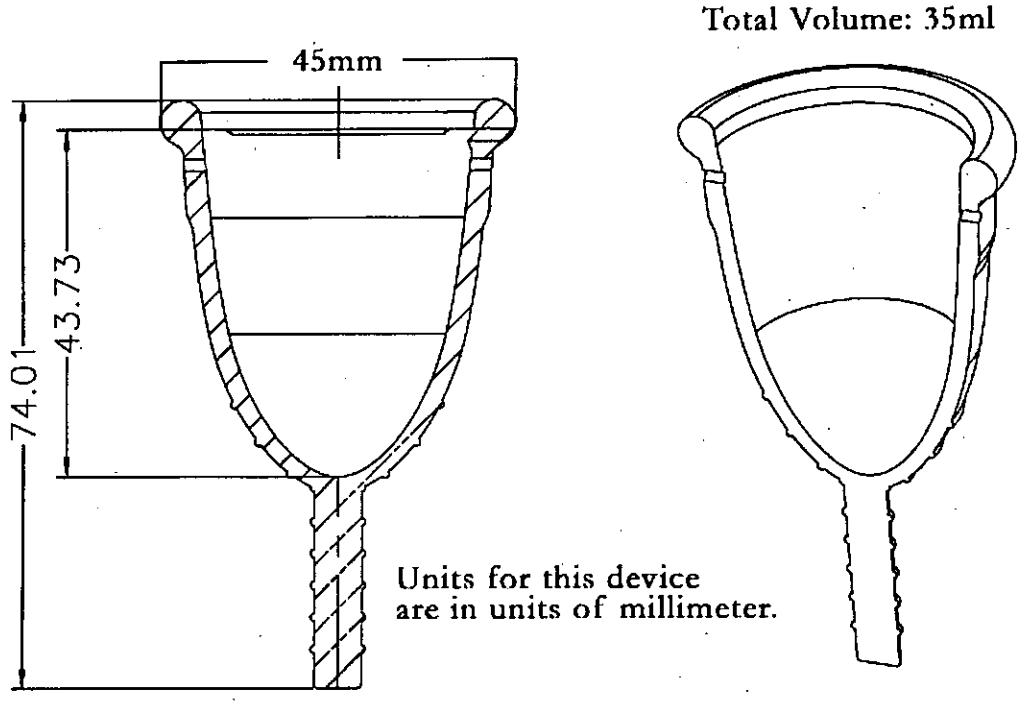
Device:

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

Intended Use of the Device:

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

Device Drawings:



Components:

The device is manufactured from a single component, LIM6040-D2 silicone elastomer, which is compliant with 21 CFR 177.2600 (Rubber articles intended for repeated use).

Biocompatibility information for the device material are exhibited in Appendix 2 – Testing.

Sterility
The BelleCup is not supplied sterile.

5. Comparison to Predicate Devices:

Technical characteristics of the device compared to the predicate device:

Feature	BelleCup	MoonCup, K040335
Manufacturer	Librette, Inc.	MoonCup, LLC
Intended Use	The device is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation. The Bellecup is placed low enough in the vagina to be retrieved readily and, at the same time, to prevent it's touching the cervix or interfering with menstrual flow through it. .	Same
Material	Soft Silicone Elastomer	Same
Sterility	Not Sterile	Same

6. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Not applicable.

7. Discussion of Clinical Tests Performed:

Not applicable

8. Conclusions:

The subject device has the same intended use and similar characteristics as the predicate device. No new questions of safety or effectiveness are raised by differences in technology or materials. Thus, the BelleCup is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Librette, Inc.
c/o Mr. Neal Kolber
Project Manager
Emergo Group
1705 S. Capital of Texas Highway, Suite 500
AUSTIN TX 78746

JUN 2 8 2010

Re: K092985
Trade/Device Name: BelleCup
Regulation Number: 21 CFR §884.5400
Regulation Name: Menstrual Cup
Regulatory Class: II
Product Code: HHE
Dated: June 6, 2010
Received: June 8, 2010

Dear Mr. Kolber:

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

INDICATIONS FOR USE

510(k) Number (if known): K092985

Device Name: BelleCup

Indications for Use: The BelleCup 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 _____ 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092985