K091754

[redacted]
November 9, 2009

Attachment D

Premarket Notification [510(k)] Summary
[As required by section 870.92(c)]

NOV 13 2009

Submitter:

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New device:

Trade or proprietary name: Lunette
Common or usual name: Menstrual Cup
Classification name of the device: 21 CFR §884.5400

Predicates:

Alicia™ Menstrual Cup (K070965)
Mooncup Menstrual Cup (K060852)

Description of the Device:

The Lunette™ menstrual cup is a soft, small internally worn reusable silicone menstrual cup that holds (instead of absorbing) monthly menstrual flow. It may remain in the body for up to 12 hours. It holds an ounce of fluid. It is available in two sizes:

- Size 1 for light flow and women who have not had intercourse (diameter of 41 mm, a height of 73 mm, and a volume of 25 ml)
- Size 2 for heavy flow (diameter of 45 mm, a height of 78 mm, and a volume of 30 ml)

The cup remains entirely within the vagina and does not touch the cervix but the stem remains outside the body to ensure retrieval of the cup. The user's guide provides information about how to use and care for the Lunette™ menstrual cup (Attachment 5).

Lunette™ menstrual cup is a re-useable internal receptacle that is placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation. Lunette™ Menstrual Cup is positioned in the lower portion of the vagina. The cup does not touch the cervix or interfere with the menstrual flow through it.

Intended Use/Indication for Use:

The Lunette™ Menstrual 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.

Conclusions:

The Lunette™ Menstrual cup (Model 1 and Model 2) have the same intended use and technological characteristics as the cleared devices (K070965 and K060852). Moreover, any differences between the Lunette™ and the predicate devices do not : (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

Substantial Equivalence:

The Lunette™ Menstrual Cup is substantially equivalent to the Alicia Menstrual Cup (K070965) and the Mooncup Menstrual Cup (K060852) in materials, dimensions, intended use and indication for use. The Lunette™ is made of silicone similar to that used in the Alicia and the MoonCup.

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

Lune Group Ltd.
% Morris Waxler, Ph.D.
President
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NOV 18 2009

Re: K091754
Trade/Device Name: Lunette Menstrual Cup / Models 1, 2
Regulation Number: 21 CFR §884.5400
Regulation Name: Menstrual cup
Regulatory Class: II
Product Code: HHE
Dated: October 5, 2009
Received: October 8, 2009

Dear Dr. Waxler:

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.

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

Attachment E

Indications for Use

510(k) Number (if known): K091754

Device Name: Lunette Menstrual Cup / Models 1, 2

Indications For Use:

The Lunette Menstrual Cup (Models 1, 2) 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 ____X___
(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)
Page 1 of _____

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091754