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K040335

Premarket Notification [510(k)] Summary
[As required by section 807.92(c)]

Submitter: Morris Waxler, Ph.D.
FDA Regulatory Affairs Specialist
LaFollette, Godfrey & Kahn
One East Main Street
Madison, WI 53701-2719
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New device:
Trade or proprietary name: MoonCup®
Common or usual name: Menstrual Cup
Classification name of the device: 21 CFR §884.5400

Predicates: DivaCup™ – Menstrual Solution (K021356)
The Keeper® (K870803)
Tassaway (K803250)

Description of the Device:

General. The MoonCup® 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:

- Style A – After childbirth;
- Style B – Before childbirth and/or C-section.

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. See the instruction brochure for information about how to use and care for the MoonCup® menstrual cup.

Material. The MoonCup® menstrual cup is manufactured from a soft silicone elastomer. The properties of the silicone are described in a master file at FDA. The Materials Data Safe Sheet (MDSS) and the Product Specifications Sheet for the silicone were submitted. The master file and the MDSS provides data on all of the biocompatibility or toxicity testing required according to FDA's memorandum to guidance G95-1. The silicone elastomer is well characterized chemically and physically and has a long history of safe use as a medical device in long-term contact with the human body.

Intended Use/Indication for Use: The MoonCup® 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 MoonCup® 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.

Substantial Equivalence

The MoonCup® is substantially equivalent to the DivaCup™ (K021356), The Keeper® (K870803), and the Tassaway (K803250) in materials, dimensions, intended use, and indication for use. The MoonCup® is made of silicone similar to the DivaCup™. The MoonCup® can hold approximately one ounce of menstrual fluid is inserted into the vagina with a stem slightly protruding to aid removal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2005

MoonCup, LLC
c/o Morris Waxler, Ph.D.
FDA Regulatory Affairs Specialist
LaFollette, Godfrey & Kahn
One East Main Street
P.O. Box 2719
MADISON WI 53701-2719

Re: K040335
Trade/Device Name: MoonCup® Menstrual Cup, Styles A and B
Regulation Number: 21 CFR §884.5400
Regulation Name: Menstrual cup
Regulatory Class: II
Product Code: HHE
Dated: March 7, 2005
Received: March 9, 2005

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 (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
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): K040335

Device Name: MoonCup®

Indications for Use: The MoonCup® 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 ✓ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040335