



**Associated  
Pharmacologists &  
Toxicologists**

April 17, 2003

**Citizen Petition**

The undersigned submit this petition under 21 CFR 10.30 of the Federal Food, Drug, and Cosmetic Act to request Dr. Mark McClellan, the Commissioner of Food and Drugs, revoke the approval for the marketing of the devices categorized as menstrual cups (21CFR 884.5400) because there is a high likelihood that the use of these devices as directed will endanger a woman's reproductive health by inducing endometriosis.

**Action Requested**

The FDA administrative record for the two menstrual cups currently marketed shows that neither was required to submit clinical data regarding their safety (see FDA Freedom of Information (FOI) Files: The Keeper: Record K870803, 1987; Instead, softcup: Record K971303, 1997 (abridged versions attached(Addendum A))). Until the manufacturers of the menstrual cups can submit suitable animal and clinical data to support that these devices can be safely used as directed without increasing the risk or severity of endometriosis, we hereby request the approval for the sale of menstrual cups be revoked.

**533 Fourth St., SE Washington, DC 20003-4222 202.544.0711**

03P-0166

CP1

## **Statement of Grounds**

### **Summary**

Menstrual cups, when used as currently recommended, can be worn for 12 hour periods during menstruation. They are designed to fit either over the cervix or within the vagina tightly enough so no menstrual debris is released from the body while a cup is in place.

Obstructions of the cervix and vagina are commonly recognized as important factors in inducing endometriosis. The cervical outlet obstruction inherent in the use of menstrual cups is likely to increase the incidence and severity of endometriosis among women who use these products.

## **Detailed Statement of Grounds**

### **Menstrual Cups and Endometriosis**

#### **A. Menstrual Cups: Approval History and Current Use**

Currently there are two menstrual cups approved for sale by the FDA: 1. The Keeper ([www.keeper.com](http://www.keeper.com)), a flexible rubber cone, that sits intravaginally to occlude menstrual discharge, and 2. Instead ([www.Softcup.com](http://www.Softcup.com)), a plastic diaphragm-shaped disc that covers the mouth of the cervix with an impermeable barrier. The Keeper is a reusable product. Instead is intended for one time use and disposal. The package inserts for both products recommend they be used for periods of time not to exceed 12 hours. The possible effect of these products on the risk of endometriosis is not mentioned in the package inserts.

The approval records for both products show that neither manufacturer was required to submit any clinical data to demonstrate their safety when used as directed (FOI Files(attached)). Thus the possible effects of these products on reproductive health have not been reviewed by the Food & Drug Administration.

Among the possible reproductive effects of the menstrual cups, there is a physiologically credible mechanism whereby their use would increase the incidence or severity of endometriosis.

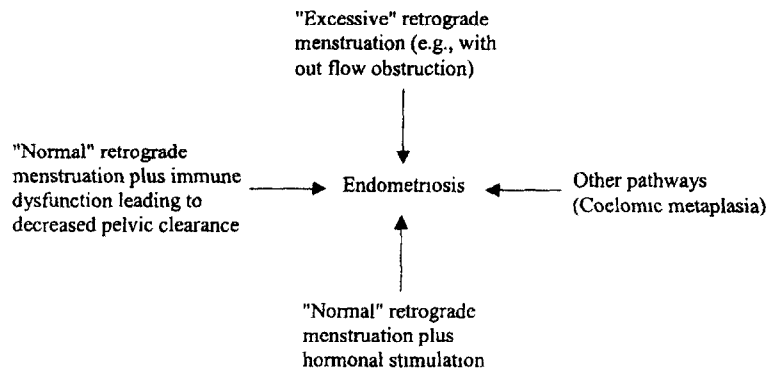
#### **B. Endometriosis**

Endometriosis is a chronic condition that is typically diagnosed clinically because of severe dysmenorrhea. Asymptomatic cases of endometriosis are often diagnosed during peritoneal surgery. In rare cases, endometriotic growths are found outside the peritoneum and the reproductive tract. Since endometriosis develops over an extended time period, the origins of this condition are subject to hypothetical explanations, and no one hypothesis appears to explain all manifestations of the disease (Guarnaccia et al, 2000; Evers, 1996; Cramer & Missmer, 2002). However, a diverse assortment of clinical and animal data are consistent with the Sampson (menstrual reflux) hypothesis for explaining the origins of peritoneal endometriosis (Sampson, 1927; Guarnaccia et al, 2000; Evers, 1996; Cramer & Missmer, 2002; D'Hooghe & Debrock, 2002). Sampson suggested that peritoneal endometriosis develops when fragments of functional endometrium are released from the surface of the uterus during menstruation and refluxed back through the Fallopian tubes to reach the peritoneal cavity. Some endometrial fragments attach to peritoneal surfaces,

growing and degenerating, cyclically, in conjunction with the menstrual cycle. These ectopic endometrial growths sometimes cause inappropriate adhesions between peritoneal tissues and organs, producing debilitating pain. When endometrial tissues occlude the fimbriated ends of the fallopian tubes, endometriosis can cause infertility.

There are several sources of clinical and experimental data that support the Sampson hypothesis and the role that "out flow obstruction" can play in the induction of endometriosis. (figure 1)

**CRAMER & MISSMER: EPIDEMIOLOGY OF ENDOMETRIOSIS**



**FIGURE 1.** Model for pathogenesis of endometriosis involving retrograde menstruation.

First, the collected anatomical analyses of the distribution of endometriotic growths in the peritoneum are consistent with the fallopian tubes as a source for the seeding tissue (Guarnaccia et al, 2000).

Second, women born with congenital defects of their reproductive tract which prevent menstrual debris from being discharged through the cervix or vagina typically develop severe forms of endometriosis (Pinsonneault O, Goldstein DP, 1985; Hanton et al, 1966; Olive &

Henderson, 1987; Geary & Weed, 1973; Farber M, Marchant, 1975; Maciulla et al, 1978; Niver et al, 1980; Nunley & Kitchin, 1980; SanFilippo et al, 1986). Some clinicians have also analyzed this population sufficiently to report that women without functional endometrial tissues (another aspect of their developmental abnormalities) do not develop endometriosis (Olive & Henderson, 1987).

Third, several observations in the baboon model for endometriosis (D'Hooghe et al, 1994; D'Hooghe et al, 1995; D'Hooghe et al., 1996) appear to support the Sampson hypothesis, and the role of out flow obstruction in the induction of endometriosis. These observations include a demonstration of the increased incidence of retrograde menstruation in baboons with spontaneous endometriosis (D'Hooghe et al., 1996); intrapelvic injection of menstrual endometrium causing experimental endometriosis similar to that observed in spontaneous disease (D'Hooghe et al, 1995); and surgically induced cervical occlusion leading to retrograde menstruation and endometriosis (D'Hooghe et al, 1994).

Retrograde menstruation appears to occur in most women (Halme & Hall, 1984). This has been demonstrated in a variety of ways, including the detection of endometrial cells in the dialysate of peritoneal dialysis patients (Blumenkrantz et al., 1981). Since retrograde menstruation is relatively common, but endometriosis appears to occur in a fraction of menstruating women, multiple factors apparently interact to produce symptomatic endometriosis. In an animal model of endometriosis, one group of researchers has demonstrated that the successful survival and growth of endometrial cells correlated directly with the amount of tissue (represented by

its weight) injected into the peritoneum (D'Hooghe et al, 1995). Additional research is being focused on the possible role that immune factors may play on the elimination of menstrual debris. In some women a defect in immunosurveillance may play a role in the clearing of menstrual debris, suggesting that women unable to clear menstrual debris go on to develop disease (Cramer & Missmer, 2002)

Epidemiological data has shown that women with early menarche, short menstrual cycles or longer periods of menstruation are more likely to suffer from endometriosis (7,8,20,22-24). These findings are consistent with the Sampson reflux hypothesis for the origin of peritoneal endometriosis. On one hand, the more frequent the challenge (i.e. in women with early onset of menstruation and those with shorter cycles) or the larger the challenge (i.e. in women with longer periods of menstruation), the more likely it is that a woman will develop endometriosis. Some clinicians also have drawn attention to epidemiological data showing a lower incidence of endometriosis among women who have given birth and suggested that the enlargement of the cervical opening (and corresponding reduction in resistance to menstrual outflow) to explain this finding (Cramer & Missmer, 2002). Dysmenorrhea is a strong risk factor for endometriosis, but it has generally been considered to represent a symptom of existing disease, since it is easy to imagine that monthly bleeding from pelvic lesions is painful. However, some data suggest that dysmenorrhea may correlate with stronger uterine contractility (Schulman et al., 1983), and one reviewer has suggested an alternate interpretation: dysmenorrhea may be associated with some degree of outflow

obstruction, caused by stronger uterine cramping, and an increased propensity to retrograde menstruation (Cramer & Missmer, 2002).

Consistent with these observations, the mechanical occlusion of the cervix or vagina during menstruation would be expected to substantially increase the retrograde flow of menstrual discharge. This mechanical occlusion would thereby increase the seeding of the peritoneal cavity with endometrial cells. Menstrual cups are, in essence, removable cervical and vaginal occlusion devices. Thus, the increased menstrual retention produced by the use of the menstrual cups is likely to have endometriosis-promoting effects.

### **C. Potential for Reflux With Menstrual Cups and Other Menstrual Products**

A clear distinction can be made between the menstrual occlusion that results from the use of menstrual cups and the occlusive potential of absorbent menstrual products such as tampons. Simply described, a menstrual absorbent product, such as a tampon, can retain the menstrual discharge within its structure until its absorbent capacity is exceeded. When a tampon is saturated, it too can become an obstructive device that would increase the reflux of endometrial tissues. However, the saturation of a tampon would also produce vaginal leakage, prompting its removal.

In contrast, menstrual cups are composed of impervious, non-absorptive materials. Since fluids are non-compressible, any discharge being held in the cavity of a menstrual cup can be readily refluxed back into the uterine cavity, as well as the fallopian tubes and eventually into the peritoneum. It should also be noted that

clinical studies using menstrual cups have shown that the debris they collect does contain viable endometrial cells (Koks et al, 1997). Although quantitative data on their effect on endometrial reflux has not yet been collected, it can be anticipated that a woman wearing a menstrual cup might inadvertently apply compressive forces and promote endometrial reflux when assuming a number of routine positions that compress the vaginal space or apply pressure to the cervical os. One of the available products (Softcup) is recommended for use during sexual intercourse. The mechanical effects on menstrual reflux in this situation also await evaluation.

In the research literature on endometriosis, one reviewer has suggested that larger fragments of endometrium may have higher invasive potential, once they enter the peritoneal cavity (Evers, 1996). Therefore, future research also needs to address whether cervical or vaginal occlusion during menstruation generates increased fluid reflux through the uterus, altering the size distribution of dislodged endometrial tissue. Available research techniques have monitored endometrial cells in peritoneal fluid during menstruation in women and in animal studies (Bartosik et al, 1986; Kruitwagen et al, 1991; D'Hooghe et al.,2001). This approach could be used to evaluate the role played by menstrual cups.

#### **D. Endometriosis Risk in Specialized Populations**

Given the concerns expressed above about how the use of menstrual cups might increase the risk of endometriosis, this adverse effect would not be expected among women who had ligated fallopian tubes. However, a review of the one adverse report involving the menstrual



cups and endometriosis in the CEDER/MAUDE database (Addendum B(attached)) shows that it involved problems apparently resulting from menstrual obstruction associated with the use of the Keeper, in a women with ligated fallopian tubes. In this case the reporting physician described the patient's uterus as "completely endometrial" and hysterectomy was recommended.

Endometriosis is a relatively common problem in teenage women. The superficial convenience of the menstrual cups for young women active in athletic competitions would make them an attractive choice for use during menstruation. However, as discussed above, until data is collected on effects of mechanical forces on the endometrial reflux associated with the use of menstrual cups, their use during strenuous activities, such as athletic competitions, is a prominent point of concern.

#### **E. Epidemiological Monitoring**

Since the onset of endometriosis is apparently influenced by a variety of factors, which include diverse elements such as individual anatomy and immune function, the epidemiology of endometriosis is not clearly defined (Cramer & Missmer, 2002). This fact suggests that the clinical demonstration of an increase in the incidence of endometriosis in association with menstrual retention devices will be a complex task, making caution even more important in this matter, while research data is being collected.

### **Conclusion**

Based on the theoretical concerns discussed above and the limited clinical reports in the FDA databases, current users of menstrual cups should be informed of the possible risk of endometriosis associated with these products, and the sale of menstrual cups as OTC devices should be discontinued until sufficient data on their safety has been collected and analyzed.

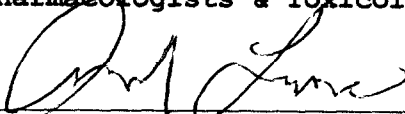
### **Environmental impact**

The petitioners claim a categorical exclusion from this requirement under Secs. 25.30 - 25.34 of 21(1) CFR.

**Certification**

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

For **Associated Pharmacologists & Toxicologists\***:

(Signature)   
 Armand Lione, Ph.D., President, APT


(Name of petitioner) Associated Pharmacologists & Toxicologists

(Mailing address) 533 - 4<sup>th</sup> St. SE Washington, DC 20003-4222

(Telephone number) (202) 544-0711

(email) ArmandLione@Hotmail.com

For **The Endometriosis Research Center**:

(Signature)   
 Heather C. Guldone, Director of Operations, ERC

(Name of petitioner) Endometriosis Research Center

(Mailing address) 630 Ibis Drive, Delray Beach, FL 33444

(Telephone number) (561) 274-7442

(email) EndoF13@aol.com

\* To whom correspondence about filing this petition should be addressed.

### References\*

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Blumenkrantz MJ, Gallagher N, Bashore RA, Tenckhoff H: Retrograde menstruation in women undergoing chronic peritoneal dialysis. *Obstet Gynecol* 57:667-70, 1981.

CEDER Adverse Event Report\*: MDR Text Key: 892088; 02/11/2000. (see addendum B, below)

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- USFDA Freedom of Information (FOI) Files (abridged)\*: The Keeper: Record K870803, 1987; Instead, softcup: Record K971303. (See Addendum A, below)

**\*Reference enclosed**

**Addendum B:  
CEDER Adverse Event Report:  
Menstrual Cups,  
APT Citizen Petition**

**CEDER/MAUDE Database Adverse Report**

<b>BRAND NAME</b>	KEEPER CUP
<b>TYPE OF DEVICE</b>	MENSTRUAL CUP
<b>MANUFACTURER (Section D)</b>	THE KEEPER CO. 3243 GLENDORA AVE. CINCINNATI OH 45220
<b>DEVICE EVENT KEY</b>	254005
<b>MDR REPORT KEY</b>	262262
<b>EVENT KEY</b>	245881
<b>REPORT NUMBER</b>	262262
<b>DEVICE SEQUENCE NUMBER</b>	1
<b>PRODUCT CODE</b>	HHE
<b>REPORT SOURCE</b>	VOLUNTARY
<b>REPORT DATE</b>	02/10/2000
<b>1 DEVICE WAS INVOLVED IN THE EVENT</b>	
<b>1 PATIENT WAS INVOLVED IN THE EVENT</b>	
<b>DATE FDA RECEIVED</b>	02/11/2000
<b>IS THIS AN ADVERSE EVENT REPORT?</b>	YES
<b>IS THIS A PRODUCT PROBLEM REPORT?</b>	NO
<b>DEVICE OPERATOR</b>	HEALTH PROFESSIONAL
<b>WAS DEVICE AVAILABLE FOR EVALUATION?</b>	NO
<b>PATIENT OUTCOME</b>	HOSPITALIZATION OTHER REQUIRED INTERVENTION
<b>ADVERSE EVENT OR PRODUCT PROBLEM DESCRIPTION</b>	
<b>REPORT DATE: 02/10/2000 MDR TEXT KEY: 892088 Patient Sequence Number: 1</b>	

PT HAD A RECENT SURGERY. PT HAS BEEN USING THE KEEPER CUP FOR ABOUT SIX YEARS. ACCORDING TO PT IT'S A MENSTRUAL CUP THAT'S WORN INTERNALLY; IT'S SOLD THROUGH MAGAZINE CLASSIFIEDS ESPECIALLY THE HERB COMPANION AND

NOW AT THEIR WEBSITE [WWW.KEEPER.COM](http://WWW.KEEPER.COM). CLICK TO USAGE TO SEE A PICTURE OF THE DEVICE. PT HAS INCREASING MONTHLY PAIN FOR THE LAST 3 YEARS. THE PAIN IS MUCH DIFFERENT FROM CRAMPS. SOMETIMES ULTRAM AND FLEXERIL DON'T EVEN "DENT" THE PAIN. LAST MONTH PT HAD ENDOMETRIOSIS SURGERY AS PART OF AN ENDOMETRIOSIS STUDY. PT'S DR FOUND VERY LITTLE ENDOMETRIOSIS; JUST WHAT HAD SLIPPED OUT AROUND THE TUBAL LIGATION PT HAD NINE YEARS AGO. WHAT PT DID FIND WAS THAT UTERUS HAS BECOME COMPLETELY ENDOMETRIAL, AS CONFIRMED BY LAB RESULTS. DR DESCRIBED UTERUS AS BLANCHING WHEN TOUCHED, LIKE YOU COULD WRITE ON IT AND SEE THE WORDS. THE DIAGNOSIS IS "ADNOMYOSIS" AND PT WAS ASKED TO START CONSIDERING A HYSTERECTOMY TO RELIEVE THE PAIN. PT WROTE THE KEEPER CUP CO. THEY SAY THIS PRODUCT HAS NEVER BEEN EVALUATED FOR ENDOMETRIOSIS. SINCE PT SEES THEM ADVERTISING A LITTLE MORE EACH YEAR, PT HOPES NO ONE ELSE HAS THE SAME OUTCOME. PT ASKS FDA TO PLEASE CONSIDER LOOKING INTO THIS. PT IS ALL FOR ALTERNATIVE HEALTHCARE WHEN IT DOES GOOD AND NO HARM.



**Associated  
Pharmacologists &  
Toxicologists**

April 2003

**Addendum A: Citizen Petition, Menstrual Cups**

FDA Records for the Approval of

**The Menstrual Cups:  
(abridged)**

**The Keeper, K870803/A**

and

**Instead, K971303**

Acquired through the FDA Freedom Of Information Office,  
11/13/02 and 01/30/03

For additional information, contact:

Armand Lione, Ph.D.  
202.544.0711  
ArmandLione@hotmail.com

**533 Fourth St., SE Washington, DC 20003-4222 202.544.0711**





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
8757 Georgia Avenue  
Silver Spring MD 20910

MAR 6 1987

Re: K870803/A

THE KEEPER

Dated: March 16, 1987

Received: March 20, 1987

Regulatory Class: II

21 CFR 884.5400

Mr. Lou Crawford  
The Keeper Company  
P.O. Box 20023  
Cincinnati, Ohio 45220

Dear Mr. Crawford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Pre-market Approval) 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 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.

Director, Division of OB-GYN, ENT,

and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

CF:17

Food and Drug Administration  
Center for Devices and  
Radiological Health  
8757 Georgia Avenue  
Silver Spring, MD 20910

MARCH 20, 1987

THE KEEPER COMPANY  
ATTN: LOU CRAWFORD  
P.O. BOX 20023  
CINCINNATI, OH 45220

D.C. Number : K870803  
Received : 03-20-87  
Product : THE KEEPER

The additional information you have submitted has been received.

-- We will notify you when the processing of your submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing you device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
8757 Georgia Avenue  
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162

Sincerely yours,

Robert I. Chissler  
Premarket Notification Coordinator  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

CP:18

OB-GYN BRANCH 510(k) REVIEW FORM

DMC Dated: 3/20/87

Date received by reviewer: 3/24/87

Control #: K870803

           original

30 day limit: 4/19/87

A amendment

90 day limit: 6/18/87

Device Name: The Keeper - Menstrual Cup

Manufacturer: The Keeper Co.

Device Description:

The device is identified as a latex rubber cup intended for vaginal insertion to collect menstrual flow.

Review Summary:

The product is equivalent to the Tassette a premarketed device.

This amendment responds to our March 11, 1987 letter requesting the chemical composition, copies of proposed product instructions and statement that the device will include the information on TSS warning identified @ 21 CFR § 801.430.

Recommendation:

Substantially equivalent

Product Code: 85 HHE

Classification: II  
@ 5884.5400

J. Michael Kusich  
Reviewer

4/15/87  
Date

J. Keene  
Branch Chief

   concur       do not concur



Memorandum

Date

From

Subject

To

REVIEWER(S) - NAME(S)

*Kuchinski*

510(k) NOTIFICATION

*K 870803/A*

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

*I checked with M. Kuchinski on effectiveness. Mike believed the "it is o.k." L. Y. 5/4/87*

The submitter requests:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Class Code w/Panel:

*85 HHE Class II  
68834.5402*

REVIEW:

*[Signature]* (DATE)

FINAL REVIEW:

*[Signature]* (DATE)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 6 1997

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ultrafem, Inc.  
% Mr. Peter S. Reichertz  
= Arent Fox Kintner Plotkin & Kahn  
1050 Connecticut Avenue, N.W.  
Washington, D.C. 20036-5339

Re: K971303  
INSTEAD® Softcup - Feminine Protection Cup  
Dated: April 7, 1997  
Received: April 8, 1997  
Regulatory class: II  
21 CFR §884.5400/Product code: 85 HHE

Dear Mr. Reichertz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

From: Reviewer(s) - Name(s) ELFA D. HARVEY /MRT

Subject: 510(k) Number K971303

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 4/15
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this device subject to the Tracking Regulation?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Was clinical data necessary to support the review of this 510(k)?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this a prescription device?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Was this 510(k) reviewed by a Third Party?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices NA
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

IF 85HAE 21CFR884.5400

Review: Colin M Pollard 0GB 6/4/97  
 (Branch Chief) (Branch Code) (Date)

Final Review: R. [Signature] for [Signature] 6/4/97  
 (Division Director) (Date)



**Associated  
Pharmacologists &  
Toxicologists**

0713

April 16, 2003

Dockets Management Branch  
US Food & Drug Administration  
Dept. Health & Human Services  
Room 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

Dear Sir or Madam:

Enclosed are four copies of a Citizen Petition to the US Food & Drug Administration regarding the medical devices known as Menstrual Cups.

Please file this petition. If there are any additional matters that need to be addressed before the petition can be filed, please contact me at the address and phone number below.

Sincerely yours,

Armand Lione, Ph.D.  
President,  
APT