

K080200

JUL 10 2008

510(k) Summary
Abbott Research Group, Inc.
WaterWorks® Douching Device

1. SUBMITTER/510(K) HOLDER

Abbott Research Group, Inc.
The Abbott Building, 235 Alpha Drive
Pittsburgh, PA 15238
Contact: Chun Lim Abbott, President & CEO
Phone: 412-426-0053

Date Prepared: January 24, 2008

2. DEVICE NAME

Proprietary Name: WaterWorks® Douching Device
Common/Usual Name: Therapeutic Vaginal Douching Apparatus
Classification Name: Douching Apparatus, Vaginal, Therapeutic

3. PREDICATE DEVICES

Good Health Premium Fountain Style Personal Douche and Enema System

4. DEVICE DESCRIPTION

The Water Works® Douching Device is a reusable system consisting of a customized 32 ounce, water container, connecting hose and a stainless steel nozzle. A hose clamp for controlling water flow through the hose and a plastic loop to attach the container to a shower head are also provided. The container is filled with tepid tap water which flows through the hose to the nozzle. The water container is hung approximately 3 feet above the vagina (eye-level).

5. INTENDED USE

The WaterWorks® is indicated for the reduction or abatement of perceived vaginal odor with or without complaints of discharge in women with no infectious cause of vaginitis.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The WaterWorks[®] Douching Device is similar in design and method of operation the predicate device, Good Health Premium Fountain Style Personal Douche and Enema System. Both systems are gravity fed and intended to be filled by the user with tap water.

7. PERFORMANCE TESTING

A comparative, randomized, and blinded multicenter clinical trial of the WaterWorks[®] and the predicate device demonstrated that the proportion of subjects in the WaterWorks[®] Group meeting the success criterion was 78 percent versus a success rate of 38.5 percent for subject in the Control Group. Fisher's exact test comparing the overall success proportions (78.0% for WaterWorks[®] versus 38.5% for Control) rejects the null hypothesis of no difference at a significance level less than 0.0001. Adverse affects on the vaginal Eco-System were quantified by changes in the lactobacillus score and the Nugent Score according to pre-defined criteria. Results for the WaterWorks[®] Group were similar to that of the Control Group. Other adverse events occurring in both Groups were also similar in nature and frequency.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Abbott Research Group, Inc.
c/o Rosina Robinson, RN, MEd, RAC
Principal Consultant, Regulatory Services
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

JUL 10 2008

Re: K080200
Trade Name: WaterWork® Douching Device™
Regulation Number: 21 CFR 884.5900
Regulation Name: Therapeutic Vaginal Douche Apparatus
Regulatory Class: II
Product Code: HED
Dated: June 2, 2008
Received: June 3, 2008

Dear Ms. Robinson:

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.



Protecting and Promoting Public Health

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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): K080200

Device Name: Water Works® Douching Device

Indications for Use:

The WaterWorks® Douching Device is indicated for the reduction or abatement of perceived vaginal odor with or without complaints of discharge in women with no infectious cause of vaginitis.

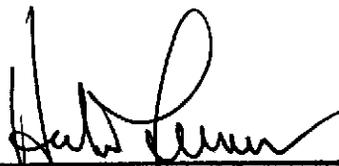
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use x
(21 CFR 807 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 K080200