MAY 2 8 2004

K030474

510(k) Summary

Device Name: Rostam pH Tampons—Plastic Applicator, Regular and Super Absorbency

Manufacturer:

Rostam Ltd.
1 Alon Hatavor St.
Caesarea Industrial Park 38900
POB 3541 Israel

Legally marketed predicate devices: These Tampons are substantially equivalent to legally marketed Rostam Plastic Applicator Tampons and Tambrands Tampax Tampon with Additive (K960341).

Device description: The Rostam pH Tampons are menstrual tampons used to absorb menstrual fluid. These Tampons will be marketed at the first stage in two absorbencies: regular and super. The Tampons reduce the usual vaginal pH increase during menses.

These Tampons are made from rayon and cotton and cotton cord. The materials used in these tampons are similar to those used in other legally marketed tampons in the US, with the exception of an additive that is designed to reduce the usual increase in vaginal pH during menstruation.

Intended Use: The Rostam pH Tampon is a menstrual tampon for the absorption of menstrual fluid. The pH Tampon reduces the usual vaginal pH increase during menses.

Non-Clinical and Clinical Testing: Preclinical toxicology information was gathered and evaluated in accordance with FDA guidance and applicable standards, including irritation testing, sensitization testing, acute oral toxicity, eye irritation, and cytotoxicity. Toxic shock syndrome toxin (TSS-1) testing was also performed according to standard methodology. The manufacturing procedures for this tampon precludes dioxin formation to ensure that levels of PCDD's and PCDF's are below the limit of detection achievable by current technology.

These tests, together with clinical evaluations, demonstrated that the tampon with additive is appropriate for its intended use.

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The Rostam pH Tampon conforms with 21 CFR 801.430 (Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency).

No materials, ingredients or chemicals not already used in legally marketed menstrual tampons in the US have been added to this tampon, including the pledget, string or plastic applicator. Only the additional chips contain chemicals that are unique in the tampon market but are well known for other medical uses. The pledget and string are fabricated according to the same specifications as the previously cleared Rostam tampons.

[1] CLD 133/979423
[1] Toxicological Evaluation Danufil V 3.6 dtex
[1] IBR 95-00-2915/00-93
[1] 21 CFR: 172.615, 175.105. 175.300, 176.180, 176.200, 176.210, 177.1200, 177.1520, 177.2600, 178.3570, 178.3850.
[1] 21 CFR: 175.105, 175.300, 177.1200, 177.1520, 179.45.
[1] Equistar Petrothene GA564000 MSDS 00000000123 10/16/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2004

Rostam, Ltd.
% Mr. Jonathan S. Kahan
Official Correspondent
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004-1109

Re: K030474
Trade/Device Name: Rostam pH Tampon Regular and Super Absorbency
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: 85 HEB
Dated: March 1, 2004
Received: March 1, 2004

Dear Mr. Kahan:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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): K030474

Device Name: Rostam pH Tampon—Regular and Super Absorbency

Indications For Use:

The Rostam pH Tampon is a menstrual tampon for the absorption of menstrual fluid. The pH Tampon reduces the usual vaginal pH increase during menses.

Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030474