

NOV 23 2004

VII

510K SUMMARY

Device Name: Rostam Scented and unscented plastic applicator Tampons
(Various Trade Tampons Sold Under Private Labels As Plastic *Applicators*)

Legally marketed device: These Tampons are substantially equivalent to legally marketed Rostam Scented and unscented Tampons with plastic applicators.

Device description: Rostam plastic applicator tampons are menstrual tampons used to absorb menstrual fluid. These Tampons will be provided with 3 absorbencies, regular, super and super plus.

These Tampons are made from rayon and/or cotton polymeric overwrap and cotton cord.

The materials used in these tampons are similar to those used in other legally marketed tampons.

Intended Use: These tampons are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Assessment of Performance Standards: Not Applicable

Non-Clinical Testing: Biocompatibility testing and safety evaluations of tampon components were historically carried out. The results of these tests demonstrate that these Tampons are equivalent in terms of safety and effectiveness to legally marketed tampons. Standard Syngyna testing confirmed the absorbency of these Tampons. In addition to the review of existing toxicological data in the public literature, the following tests were conducted and are relevant to the safety of Rostam plastic applicator tampons.

◇ **Repeated Insult Patch Test, 100 human subjects**

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 2004

Rostam Ltd.
% Robert J. Staab, Ph.D.
Official Correspondent
Regulatory and Technical Associates, Inc.
73 Franklin TPK.
ALLENDALE NJ 07401

Re: K042773
Trade/Device Name: Rostam Ltd. Fragranced or
Unfragranced New Plastic Applicator Tampons
Regulation Number: 21 CFR 884.5460
Regulation Name: Scented or scented deodorized
menstrual tampon
Regulation Number: 21 CFR 892.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: 85 HIL and HEB
Dated: September 20, 2004
Received: October 5, 2004

Dear Dr. Staab:

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.

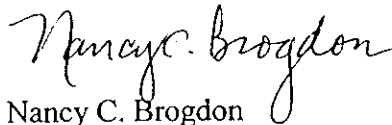
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

Device Name: Rostam Ltd. Fragranced or Unfragranced New Plastic Applicator Tampons

Indications For Use:

As a Class II Device, the menstrual tampon is defined as follows: (21CFR884.5460 and 21CFR 884 5470).

Rostam Ltd. Fragranced plastic applicator tampons are a plug of Cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge.

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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042773

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