K090071

MAY 28 2009

ATTCH 6, amended

VII 510K SUMMARY

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

Legally marketed device: These Tampons are substantially equivalent to legally marketed Tampax Compak Pearl 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, Light, regular and super.

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: The Rostam Fragranced and Unfragranced Compact Applicator Tampons are inserted into the vagina and used to absorb menstrual or other vaginal discharge.

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**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2009

Rostam Limited
c/o Robert J. Staab, Ph.D.
Official Correspondent
Regulatory and Technical Associates (RTA)
30 Neck Road
OLD LYME CT 06371

Re: K090071
Trade/Device Name: Rostam Fragranced and Unfragranced Compact Applicator Tampons
Regulation Number: 21 CFR §884.5460
Regulation Name: Scented or scented deodorized menstrual tampon
Regulatory Class: II
Product Code: HIL and HEB
Dated: May 2, 2009
Received: May 11, 2009

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

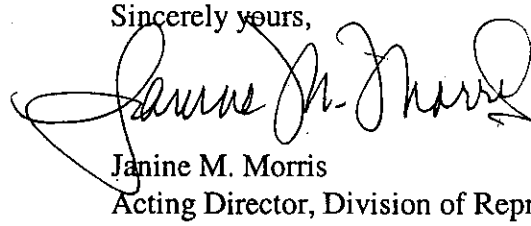
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTCH 5, amended

Applicant: Rostam Ltd

510(k) Number K090071

Device Name: Rostam Ltd Fragranced and Unfragranced Compact Applicator Tampons.

Indications For Use:

The Rostam Fragranced and Unfragranced Compact Applicator Tampons are inserted into the vagina and used to absorb menstrual or other vaginal discharge

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090071

Over-the-Counter Use ✓