MAY 0 9 2002 K020535

VII 510K SUMMARY

Device Name: ROSTAM Interlude and Other Private Label Plastic Applicator Tampons

Legally marketed device: These Tampons are substantially equivalent to legally marketed predicate tampons with applicators.

Device description: Rostam Interlude Plastic Applicator Tampons are menstrual tampons used to absorb menstrual fluid. These Tampons will be marketed in three absorbencies: regular, super and super plus.

These Tampons are made from rayon and cotton and cotton cord.

The material used in these tampons are similar to those used in other legally marketed tampons in the US.

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.

- ◊ **irritation testing**
- ◊ **sensitization testing**
- ◊ **acute oral toxicity**
- ◊ **eye irritation testing**
- ◊ **cytotoxicity testing**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 9 2002

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

Re: K020535
Trade/Device Name: Interlude Tampons and Other Under Private Label
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: 85 HEB
Dated: February 15, 2002
Received: February 19, 2002

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 (PMA), 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 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.

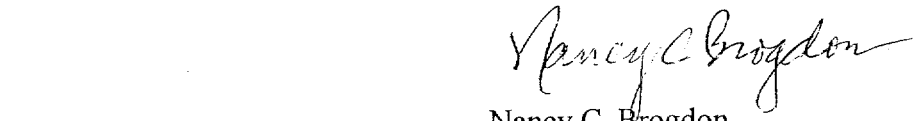
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

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" (21 CFR Part 807.97). 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K020535

Page ___ of ___

510(k) Number (if known): K020535 ~~applied for~~

Device Name: Interlude and other private label plastic applicator tampons

Indications For Use:

As a Class II device, the menstrual tampon is defined as follows: (21 CFR 884.5460 and 21 CFR 884.5470)

Rostam applicator tampons are made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other discharge.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020535