Robert J. Staab Ph.D.
President

(860) 434 5872
(860) 434 5892 ph/fx

NOV 1 0 2010

RTA

Regulatory and Technical Associates
30 Neck Road
Old Lyme CT 06371
Official Correspondent for Rostam

Prepared 11/10/10

VII **510K SUMMARY**

Device Name: Rostam Scented and unscented plastic biodegradable 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. They are Class II devices, 21 CFR 884.5460 and 21 CFR 884.5470. The predicate tampons have been marketed under K 042773 and K062001.

Regulation Name: (Unscented menstrual tampon & Scented menstrual tampon), regulation number (21 CFR 884.5470 & 21 CFR 884.5460), and procode (HEB & HIL)

Device description: Rostam plastic scented and unscented biodegradable applicator tampons are being submitted to obtain clearance for a new material applicator. They are menstrual tampons used to absorb menstrual fluid. These Tampons will be provided with 4 absorbencies, light, regular, super and super plus.
These Tampons are made from rayon and/or cotton (as the absorbent material) polymeric overwrap, cotton/polyester sewing thread and cotton cord.

Intended Use:
The materials used in these tampons are similar to those used in the predicate device, a legally marketed tampon and the Intended Use: These tampons are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid is the same as in the predicate device a legally marketed tampon.

Technological Characteristics.
The subject and predicate device have different technological characteristics, as a result of the new material applicator. The new applicators are biodegradable.

PERFORMANCE 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 Syngina 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 biodegradable applicator tampons.

Cytotoxicity, rabbit vaginal irritation assays with saline and cottonseed oil, rabbit skin irritation assays with saline and cottonseed oil were carried out to substantiate safety of the biodegradable applicator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

NOV 10 2010

Re: K102445
Trade Name: Rostam Ltd Scented and Unscented Biodegradable Plastic Applicator Tampons
Regulation Number: 21 CFR §884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: August 23, 2010
Received: August 26, 2010

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 0 2010

Indications for Use Form

Indications for Use

510(k) Number (if known): _K102445

Device Name:Rostam Ltd Scented and Unscented Biodegradable Plastic Applicator Tampons

Indications for Use:

The Rostam Scented and Unscented Biodegradable Plastic Applicator Tampons are 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 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102445