K023479

NOV 2 6 2002

VII 510K SUMMARY

Device Name: "Femtex" Tampons and other Private Label Plastic Applicator Tampons

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

Device description: First Quality Hygienic Plastic Applicator Tampons are menstrual tampons used to absorb menstrual fluid. These Tampons will be marketed in four absorbencies: junior regular, super and super plus.

These Tampons are made from rayon 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 of raw materials were historically conducted and are relevant to the safety of First Quality Hygienic plastic applicator tampons.

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

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Menstrual Tampon

VIII Substantial Equivalence Comparison Chart

Comparison Element	New device	Predicate Device
Device Name	First Quality HygienicPrivate label plastic applicator tampons	Kotex plastic applicator tampons
Manufacturer	First Quality Hygien..	Kimberly Clark
510 (k) #	requested	K896994
Intended Use	Absorb Menses Intravaginally	Absorb Menses Intravaginally
Device Design	spec. Junior 1.80 g 35mm Reg. 2.20g, c.44mm Sup. 3.30 g c. 45 mm SupPl. 3.6 g, 53 mm cord, 125 mm (all)	Kotex est. Reg 2.30 g, 42 mm Sup. 3.30 g, 45 mm SupPl.c.4.4g, 55 mm cord, 130 mm (all)
Component Materials ,	plug:rayon PEG stearate palmitate, or polyoxyethylene 20 sorbitan monolaurate	plug: rayon/cotton mix fatty acid polyglycol ester/fatty alcohol poly-glycol ether, Leomin, glycerol finishes
	sewing thread: cotton	sewing thread: cotton
	w/drawal cord: cotton w/ paraffinic wax base	w/drawal cord: cotton w/ paraffinic base
Applicator	food grade polyethylene linear	food grade polyethylene linear mix

Absorbency range in grams per Syngyna methodology

	junior	regular/	super	super plus
maximum	6	9	12	15
minimum	-	6	9	12
required accessory devices	none	none	none	none
Other features	none	none	none	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2002

First Quality Hygienic, Inc.
% Robert J. Staab, Ph.D
Official Correspondent
Regulatory and Technical Associates
73 Frankllin TPK
ALLENDALE NJ 07401

Re: K023479
Trade/Device Name: "Femtex" Tampons and other Private Label Plastic Applicator Tampons
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: 85 HEB
Dated: October 17, 2002
Received: October 17, 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

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023479

Device Name: First Quality Hygienic and other private label plastic applicator tampons.

Indications For Use:

INDICATIONS FOR USE

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

First Quality Hygienic plastic applicator tampons are a plug made of cellulosic or synthetic material that is 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)

David G. Segura

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K023479

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓

(Optional Format 1-2-