JUL 14 2003

510K SUMMARY K031067

Device Name: Private Label and Femtex Open-End Tampons

Legally marketed device: These Femtex Junior and Slender Regular Tampons are substantially equivalent to legally marketed Femtex tampons with open-end applicators.

Device description: Femtex Junior and Slender Regular Tampons are menstrual tampons used to absorb menstrual fluid. These Femtex Open-End Tampons will be provided with 2 absorbencies: Slender Regular and Junior.

Femtex Open-End Junior and Slender Regular Tampons are made from rayon absorbent, cotton cord and cotton sewing thread.

The material used in Femtex Open-End Junior and Slender Regular Tampons are similar to those used in other legally marketed tampons.

Intended Use: Femtex Open-End Junior and Slender Regular 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: Biocompatability testing of the Femtex Junior and Slender Regular Tampons' components was reviewed. The results of these tests demonstrate that the Femtex Tampons are equivalent in terms of safety and effectiveness to legally marketed tampons. Standard Syngyna testing confirmed the absorbency of the Femtex Tampons. In addition to the review of existing toxicological data in the public literature, the following tests have been conducted on components relevant to the safety of Femtex tampons.

- ◊ **irritation testing**
- ◊ **oral toxicity testing**
- ◊ **cytotoxicity testing**

***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2003

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

Re: K031067
Trade/Device Name: First Quality Hygienic and Other Private Label Slender Regular and Junior Tampons
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampons
Regulatory Class: II
Product Code: 85 HEB
Dated: April 2, 2003
Received: May 30, 2003

Dear Dr. Stabb:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

Ver/ 3 - 4/24/96

K031067

Applicant: First Quality Hygienic

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

Device Name: First Quality Hygienic and other Private Label Slender Regular and Junior tampons

Indications For Use:

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

First Quality Hygienic slender regular and Junior 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)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031067

Over-The-Counter Use ✓