

K051446

JUL 14 2005

### 510K SUMMARY

**Device Name:** Femtex and Private Label Scented Plastic Applicator Tampons

**Legally marketed device:** These Femtex and Private Label Scented Plastic Applicator Tampons are substantially equivalent to legally marketed Femtex and Other Private label Scented Plastic Applicator tampons (K032173).

**Device description:** Femtex and Private Label Scented Plastic Applicator Tampons are menstrual tampons used to absorb menstrual fluid, with fragrance added for aesthetic purposes. The tampons will be provided in five (5) styles/absorbencies: Light, Slender Regular, Regular, Super and Super Plus with a plastic applicator.

Femtex and Private Label Scented Plastic Applicator Tampons are made from rayon absorbent, cotton cord and cotton sewing thread, and added fragrance.

The material used in Femtex and Private Label Scented Plastic Applicator Tampons are similar to those used in other legally marketed tampons.

**Intended Use:** Femtex and Private Label Scented Plastic Applicator 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 of the Femtex and Private Label Scented Plastic Applicator Tampons was reviewed. The results of these tests demonstrate that the 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 have been conducted on components relevant to the safety of Femtex scented plastic applicator tampons.

- ◇ sensitization testing
- ◇ vaginal irritation testing

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 14 2005

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

Re: K051446  
Trade/Device Name: Femtex and Private Label Scented  
Plastic Applicator Tampons  
Regulation Number: 21 CFR 884.5460  
Regulation Name: Scented or scented deodorized  
menstrual tampon  
Regulatory Class: II  
Product Code: HIL  
Dated: May 31, 2005  
Received: June 29, 2005

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 (Premarket Approval), it may be subject to such 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.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

## Indications for Use

510(k) Number (if known): Applied for K051446

Device Name: First Quality Hygienic, Inc. Femtex and Private Label Scented Plastic Applicator Tampons

Indications For Use:

As a Class II Device, the menstrual tampon is defined as follows: (21CFR884.5460 and 21CFR 884 5470).

First Quality Hygienic, Inc. Femtex and Private Label Scented plastic applicator tampons are a plug of Cellulosic or synthetic material that is 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 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K051446

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