DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 2, 2015

First Quality Hygienic, Inc.
% Dave Yungvirt
Official Correspondent
45 Rockerfeller Plaza, Suite 2000
New York, NY 10111

Re: K151470
Trade/Device Name: Opal by Femtex and Private Label Unscented Compact Applicator Tampon, Light Absorbency; Opal by Femtex and Private Label Unscented Compact Applicator Tampon, Regular & Super; Opal by Femtex and Private Label Unscented Compact Applicator Tampon, Super Plus; Opal by Femtex and Private Label Unscented Compact Applicator Tampon, Super Absorbency
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: October 14, 2015
Received: October 19, 2015

Dear Dave Yungvirt,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151470

Device Name
Opal by Femtex and Private Label Unscented Compact Applicator Tampon - Light Absorbency, Regular Absorbency, Super Absorbency, and Super Plus Absorbency

Indications for Use *(Describe)*
Unscented tampon for women's personal hygiene with respect to intra vaginal absorption of menstrual or other vaginal discharge. The plastic applicator is for easing the placement of the tampon correctly into the vagina.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5 – 510(k) Summary

1. **Submitter's name and address:**
   First Quality Hygienic, Inc.
   121 North Road
   McElhattan, PA 17748

2. **Submitter's telephone number and fax number:**
   Tel: 516-498-3665
   Fax: 516-829-4949

3. **Contact person:**
   Melanie Leibowitz
   Director of Regulatory Affairs

4. **Date this 510(k) summary prepared:**
   04/23/2015

5. **Regulatory Description:**

Trade name:	Opal by Femtex and Private Label Unscented Compact Applicator Tampon
Common Name:	Unscented Menstrual Tampon
Classification Name:	Tampon, Menstrual, Unscented
Regulation Description:	Unscented Menstrual Tampon
Regulation Number:	21 CFR 884.5470
Class:	II
Product Code:	HEB

6. **Legally marketed device to which substantial equivalence is claimed:**
   Tosama Hygiene Tampon (Tosama Maxim Compact Plastic Applicator Tampon), K080775

7. **Description of the device:**
   The Opal by Femtex and Private Label Unscented Compact Applicator Tampons is an unscented, compact applicator menstrual tampon. The tampon itself is made of a strip of viscose fibers in which a cord is inserted and pressed firmly together. The viscose tampon is covered with a thin layer of non-woven fiber material which is melted on the strip. The applicator tubes are made from polyethylene (PE). The tampon with applicator is

wrapped in printed polypropylene (PP) wrapping. The tampon is marketed in Light, Regular, Super, and Super Plus Absorbencies.

8. Intended use and indication for use:

For over-the-counter use: Unscented tampon for women's personal hygiene with respect to intra vaginal absorption of menstrual or other vaginal discharge. The plastic applicator is for easing the placement of the tampon correctly into the vagina.

9. Summary of technological characteristics compared to the predicate device:

	Opal by Femtex and Private Label Unscented Compact Applicator Tampon		**Tosama Hygiene Tampon K080775**	
Classification Regulation	884.5470		884.5470	
Product Code	HEB		HEB	
Intended Use	Unscented tampon for women's personal hygiene with respect to intra vaginal absorption of menstrual or other vaginal discharge. The plastic applicator is for easing the placement of tampon correctly into the vagina.		Unscented tampon for women's personal hygiene with respect to intra vaginal absorption of menstrual or other vaginal discharge. The plastic applicator is for easing the placement of tampon correctly into the vagina.	
Sterile?	No		No	
Design	Compact tampon with mushroom-shaped tip and straight grooves		Compact tampon with mushroom-shaped tip and straight grooves	
Absorbency, grams	Light	≤ 6.0	N/A	
	Regular	6.0 - 9.0	Regular	6.0 - 9.0
	Super	9.0 - 12.0	Super	9.0 - 12.0
	Super Plus	12.0 - 15.0	Super Plus	12.0 - 15.0
Pledget Length Dimensions (mm)	Light	40.0 – 45.0	N/A	
	Regular	40.0 – 45.0	Regular	45.0 - 49.0
	Super	43.0 – 46.0	Super	45.0 - 49.0
	Super Plus	43.0 – 46.0	Super Plus	46.0 - 50.0
Pledget Diameter Dimensions (mm)	Light	8.7 – 9.7	N/A	
	Regular	8.7 – 9.7	Regular	11.0 - 13.0
	Super	11.0 – 13.0	Super	11.0 - 13.0
	Super Plus	13.0 – 15.0	Super Plus	13.0 - 15.0
Applicator Inner Tube Length x Diameter	Light	66.0 - 68.0 x 10.5 - 11.5	N/A	

Dimensions (mm)		Regular	66.0 - 68.0 x 10.5 - 11.5	Regular	66.5 x 18.0
		Super	64.0 - 66.0 x 13.5 - 14.5	Super	66.5 x 18.0
		Super Plus	65.5 - 68.5 x 15.5 - 16.5	Super Plus	66.5 x 21.4
Applicator OuterTube Length x Diameter Dimensions (mm)		Light	58.0 x 60.0 x 13.0 - 14-0	N/A	
		Regular	58.0 x 60.0 x 13.0 - 14-0	Regular	59.5 x 18.9
		Super	59.0 x 61.0 x 15.0 - 16.0	Super	59.5 x 18.9
		Super Plus	60.0 x 62.0 x 17.0 - 18.0	Super Plus	59.5 x 22.7
Cotton Cord		100% Hydrophobic Cotton		100% Hydrophobic Cotton	
Nonwoven		PET/PE – conforms with 21 CFR 177-178		PET/PE – conforms with 21 CFR 177-178	
Applicator Tube	Plastic	Low Density Polyethylene		Low Density Polyethylene	
	Colorant	Four new colorants, for Green, Pink, Blue, and Pearl White applicator tubes; New colorants have the following characteristics: • Meets Toxics Substance Control Act Inventory (TSCA) • 21 CFR 178.3297 and/or EU Resolution (89)1 compliant; Extractables testing confirmed that no harmful compounds are bioavailable • conforms with 21 CFR 177-178		Pearl White colorant with the following characteristics: • Meets Toxics Substance Control Act Inventory (TSCA) • 21 CFR 178.3297 and/or EU Resolution (89)1 compliant; Extractables testing confirmed that no harmful compounds are bioavailable • conforms with 21 CFR 177-178	
	Mold Release Agent	Food grade mold release agent—conforms with 21 CFR 177-178		Food grade mold release agent—conforms with 21 CFR 177-178	
	Antistatic Agent	Food grade antistatic agent—conforms with 21 CFR 177-178		N/A	
Wrapper (Primary Packaging)		Polypropylene		Polypropylene	

10. Non-Clinical Performance Data

The following testing was performed:

Absorbency

Absorbency testing for the new device was performed per the 21 CFR 801.430 for Syngina absorbency testing. Data for each absorbency were then analyzed for 90% population distribution at 90% confidence, as the regulation directs, and it was confirmed that 90:90 ranges of Light, Regular, Super, and Super Plus absorbencies met the absorbency range requirements defined by 21 CFR 801.430.

Chemical residues

2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) and 2,3,7,8-tetrachlorofuran dioxin (TCDF) testing was performed on the new device per European Community (EC) Regulation 589/2014 (for food) and EC Regulation 709/2014 (for feed). No TCDD or TCDF was detectable by this method.

Pesticide (including herbicides) testing was performed on the new device per method ASU L00.00-34. No pesticides (including herbicides) were detected.

Extractables testing was performed on the new device according to ISO 10993-12: 2012, *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*, and ISO 10993-18: 2005, *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*. No extractable chemicals were detectable in the aqueous extraction, which most closely simulated physiological conditions. Very low levels of non-toxic extractables were obtained in harsh, non-physiologically relevant organic extraction conditions.

Withdrawal cord attachment test

Withdrawal cord attachment strength testing for the new device was performed per Australian Standard AS/NZS 2869:1998, *Tampons—Menstrual*. Each tampon tested for every absorbency level met the Standard's minimum attachment strength requirement of 22.4 Newtons (N). Each absorbency data set met an average value of ≥ 28N, which is the Standard's requirement for each production lot.

Fiber Shed Testing

Fiber shed testing for the new device was evaluated using an internal fiber shed test protocol, since no recognized standard is available. The new device does not exhibit the potential to shed more fiber than the predicate device.

Biocompatibility Testing

Biocompatibility assessment for the new device was evaluated in accordance with the May 1, 1995 FDA Blue Book Memorandum #G95-1, *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'* and ISO 10993-1:2003, *Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process*. Biocompatibility requirements were assessed for the tampon as having "limited contact" (*i.e.*, < 24 hrs) and as a surface device, contacting the skin and mucous membrane. The battery of testing included the following tests:

- Cytotoxicity
- Intracutaneous irritation
- Acute systemic toxicity

Pre-clinical microbiological testing

Preclinical microbiology evaluation was performed for the new device in as recommended by the July 27, 2005 Guidance, *Guidance for Industry and FDA Staff, Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)*. The following pre-clinical microbiology tests were considered:

- Bioburden

  Bioburden was evaluated for the new device per European Pharmacopeia 5.1.4, *Microbiological Quality of Pharmaceutical Preparations*, Category 2. No more than 29 colony forming units (CFU) of aerobic bacteria were identified on any sample tested. Furthermore, zero yeasts and no more than 5 mold CFUs were found on any sample tested. Finally, no *Pseudomonas aeruginosa, Staphylococcus aureus,* and enterobacteria or other gram negative bacteria were detected.

- Bacteriostatic effect on *Staphylococcus aureus*

  Effect of the new device on growth of *Staphylococcus aureus* was evaluated using adaption of method United States Pharmacopeia (USP) 30, Chapter 51 (2007): *Antimicrobial Effectiveness Testing*. The test article did not demonstrate the potential to enhance *S. aureus* growth.

- Effect on normal vaginal microflora growth

  Effect of the new device on the growth of normal vaginal microflora was evaluated per USP 31, Chapter 71(2008): *Sterility Tests*. The new device did not demonstrate the potential to inhibit the growth of normal vaginal microflora.

- Effect on production of *S. aureus* Toxic Shock Syndrome Toxin-1 (TSST-1)

  The new device was evaluated to determine its impact on the production of TSST-1 by *S. aureus*. Evaluation was performed using a Tampon Sac Method with TSST-1 production detected by enzyme-linked immunosorbant assay (ELISA) and subsequent plate counting to enumerate CFUs. The new device does not demonstrate the potential to augment TSST-1 relative to current legally marketed tampons.

11. Conclusion

The Opal by Femtex and Private Label Unscented Compact Applicator Tampon characteristics and comparisons detailed above demonstrate that the new device has the same fundamental design, Indications for Use, technology, and performance specifications as the predicate device. Non-Clinical Performance Testing demonstrates that the new device meets the absorbency requirements defined by 21 CFR 801.430, which confirms the device's effectiveness for the Indications for Use. Biocompatibility testing, Pre-Clinical Microbiology testing, and Withdrawal Cord Attachment Strength and Fiber Shed testing demonstrate that the new device has a safe biocompatibility profile, does not increase the potential to promote TSS relative to the predicate device, and has a tampon integrity profile that is equivalent to the predicate device. Furthermore, Extractables testing demonstrates that the applicator and tampons do not have the potential to expose the user to harmful chemicals. Altogether, then, the data support the conclusion that the Opal by Femtex and Private Label Unscented Compact Applicator Tampon is substantially equivalent to the predicate device and is safe and effective for its Indications for Use.