August 28, 2019

Jiangsu YOAI Technology Co., Ltd.
c/o Field Fu
Official Correspondent
Shenzhen Joyantech Consulting Co., Ltd.
Room 1122, No. 55 Shizhou Middle Road,
Nanshan District
Shenzhen, GD755 Guangdong
CHINA

Re: K182142
Trade/Device Name: FEMME Applicator Tampon
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: July 10, 2019
Received: July 29, 2019

Dear Field Fu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon Andrews
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182142

Device Name
FEMME Applicator Tampon

Indications for Use *(Describe)*
The FEMME Applicator Tampon is an 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. Submission Sponsor

Applicant Name	Jiangsu Yoai Technology Co., Ltd.
Address	Building No.3, No.33 Jing You Road, Jiangning District, Nanjing, Jiangsu, China
Phone No.	86-025-69620808
Contact Person	Ms. Huan Wang
Email	huan.wang@yoai.com
Date Prepared	August 22, 2019

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	Room 1122, No.55 Shizhou Middle Road, Nanshan District, Shenzhen, Guangdong, P.R.China
Post Code	518000
Phone No.	86-755-86069197
Contact Person	Mr. Field Fu; Ms. Jessie You; Ms. Elly Xu
Email	Jessie@cefda.com; elly@cefda.com

3. Device Identification

Trade name	FEMME Applicator Tampon
Common name	Unscented Menstrual Tampon
Specifications	Regular, Super and Super plus
Classification	II
Classification name	Tampon, Menstrual, Unscented
Product code	HEB
Regulation Number	21 CFR 884.5470

4. Predicate Device Information

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 (K151470). The predicate device has not been subject to a design-related recall.

5. Device Description

The FEMME Applicator Tampon is an unscented, menstrual tampon. The tampon is comprised of an absorbent viscose pledget, an overwrap, a removal string, and an applicator. The applicator contains 3 parts: a barrel, grip, and plunger. The tampon was designed as a compact tampon with a mushroom-shaped tip. The pledget is of the traditional cylindrical bullet-like shape and is covered with a thin layer of overwrap. The applicator has a standard rounded and smooth tip to ease insertion. Each tampon is individually wrapped and packaged in multi-unit container for retail sale. There are 3 specifications of tampon with different absorbencies: Regular, Super and Super plus. Each absorbency specification has a different color removal string and applicator.

6. Indications for Use Statement

The FEMME Applicator Tampon is an 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.

7. Substantial Equivalence Discussion

	Subject Device	**Predicate Device**
	FEMME Applicator Tampon	**Opal by Femtex and Private Label Unscented Compact Applicator Tampon**
510(k) number	K182142	K151470
Classification	884.5470	884.5470

Jiangsu Yoai Technology Co., Ltd.

Subject device: FEMME Applicator Tampon

Regulation				
Product Code	HEB		HEB	
Indications for use	The FEMME Applicator Tampon is an 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.		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.	
Components	The FEMME Applicator Tampon is comprised of an absorbent pledget and an applicator.		The Unscented Compact Applicator Tampon is comprised of an absorbent pledget and an applicator.	
Sterile?	No		No	
Design	Compact tampon with mushroom-shaped tip and straight grooves.		Compact tampon with mushroom-shaped tip and straight grooves.	
Syngyna Absorbency, grams	N/A		Light	⩽ 6.0
	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 (mm)	N/A		Light	40.0 – 45.0
	Regular	42.0 – 52.0	Regular	40.0 – 45.0
	Super	47.0 – 52.0	Super	43.0 – 46.0
	Super plus	47.0 – 52.0	Super plus	43.0 – 46.0
Pledget diameter	N/A		Light	8.7 – 9.7
	Regular	10.6 – 12.6	Regular	8.7 – 9.7
	Super	12.0 – 14.0	Super	11.0 – 13.0
	Super plus	14.0 – 16.0	Super plus	13.0 – 15.0
	N/A		Light	66.0 – 68.0 x 10.5 – 11.5
Applicator length x diameter (mm, Inner	Regular	78.5 – 79.5 x 6.4 – 6.5	Regular	66.0 – 68.0 x 10.5 – 11.5

tube-plunger)		Super	78.5 – 79.5 x 6.4 – 6.5	Super	64.0 – 66.0 x 13.5 – 14.5
		Super plus	78.5 – 79.5 x 6.4 – 6.5	Super plus	65.5 – 68.5 x 15.5 – 16.5
Applicator length x diameter (mm, Outer tube)		N/A		Light	58.0 – 60.0 x 13.0 – 14.0
		Regular	77.0 – 78.0 x 14.5 – 15.0	Regular	58.0 – 60.0 x 13.0 – 14.0
		Super	77.0 – 78.0 x 14.5 – 15.0	Super	59.0 – 61.0 x 15.0 – 16.0
		Super plus	77.5 – 78.5 x 16.5 – 17.0	Super plus	60.0 – 62.0 x 17.0 – 18.0
Removal String		Cotton, Polyester Violet, green, and blue colorants with the following characteristics: • 21 CFR 178.3297 compliant		100% Hydrophobic Cotton	
Pledget		Viscose		Viscose	
Overwrap		Polyester, Polyethylene		Polyethylene/Polyethylene terephthalate	
Wrapper (Primary Packaging)		Polyethylene		Polypropylene	
Applicator Tube	**Plastic**	Low Density Polyethylene (LDPE), Thermoplastic elastomer		Low Density Polyethylene	
	Colorant	Purple, green, and blue colorants with the following characteristics:		Green, Pink, Blue, and Pearl White colorants 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	N/A	Food grade mold release agent—conforms with 21 CFR 177 – 178
	Antistatic Agent	N/A	Food grade antistatic agent—conforms with 21 CFR 177 – 178

8. Non-Clinical Performance Data

The evaluation is in accordance with FDA guidance: Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s).

8.1 Biocompatibility testing

Biocompatibility assessments for the FEMME Applicator Tampon were conducted in accordance with FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*. Biocompatibility testing was selected for a surface contacting device having “limited contact” (i.e., < 24 hrs) with intact skin and mucous membranes. The battery of testing included the following tests:

A. FEMME Applicator Tampon – applicator
   1) In Vitro Cytotoxicity (ISO 10993-5: 2009)
   2) Intracutaneous study (ISO 10993-10: 2010)
   3) Guinea pig maximization sensitization study (ISO 10993-10: 2010)

B. FEMME Applicator Tampon – pledget
   1) Cytotoxicity study (ISO 10993-5: 2009)
   2) Vaginal irritation study (ISO 10993-10: 2010)
   3) Guinea pig maximization sensitization study (ISO 10993-10: 2010)
   4) Systemic toxicity study (ISO 10993-11: 2017)

8.2 Performance testing – Bench

The performance tests were conducted to demonstrate the effectiveness of device:

A. Microbiological testing:

1) Bioburden (ISO 11737-1: 2006): the bioburden of the subject device was 5.6 CFU/tampon;

2) The effect of tampon on growth of normal vaginal microflora (USP 71): the subject device does not alter the growth of normal vaginal microflora;
3) The effect of tampon on growth of *Staphylococcus aureus* (USP 71): The subject device does not enhance the growth of *Staphylococcus aureus (S. aureus)* compared to an *S. aureus* control;
4) The effect of tampon on production of *S. aureus* TSST-1: the subject device did not increase production of Toxic Shock Syndrome Toxin-1 (TSST-1) compared to an *S. aureus* control.

B. Chemical residue testing:
   1) Polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans residues (PCDD/Fs) testing was performed on the subject device per EPA 1613B:1997: PCDD/Fs concentrations were N.D. (not detectable).
   2) Pesticide and Cl residue testing was performed on the subject device per EN 15662: 2008: Pesticides and Cl residue concentrations were N.D. (not detectable).

C. Physical performance testing:
   1) Absorbency testing for the FEMME Tampon Applicator was performed per the 21 CFR 801.430 Syngyna absorbency protocol. The absorbency ranges for all specifications met the requirements of 21 CFR 801.430.
   2) Removal string strength for the subject device was performed per AS/NZS 2869: 1998. 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 $\geqslant$ 28 N, which is the standard's requirement for each production lot.
   3) Fiber shedding testing was evaluated using internal protocols, since no recognized standard is available. The subject device does not exhibit the potential to shed more than the predicate fiber.
   4) Tampon integrity was evaluated using internal protocols, since no recognized standard is available. The subject device meets the visual and observational requirements set for an acceptable subject device.

9. Conclusion

The FEMME Applicator Tampon characteristics and comparisons detailed above demonstrate that the subject 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, microbiology testing, and physical performance 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. The data support the conclusion that the FEMME Applicator Tampon by Jiangsu Yoai Technology Co., Ltd. is substantially equivalent to the predicate device and is safe and effective for its Indications for Use.