May 9, 2019

Qingdao Youjia Hygiene Technology Co., Ltd
% Jessie You
Official Correspondent
Shenzhen Joyantech Consulting Co., Ltd
Room 1122, No.55 Shizhou Middle Road, Nanshan District
Shenzhen, Guangdong 755
China

Re: K190218
Trade/Device Name: BiuBiu Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: January 26, 2019
Received: February 4, 2019

Dear Jessie You:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason Roberts -S

for
Sharon M. 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)*
K190218

Device Name
BiuBiu Tampon

Indications for Use *(Describe)*
The BiuBiu tampon is inserted into the vagina and used to absorb menstrual and other vaginal discharge.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K190218 - 510(k) Summary

1. Submission Sponsor

Applicant Name	Qingdao Youjia Hygiene Technology Co., Ltd
Address	No. 778 Mingyue Road, Huangdao Zone, Qingdao, China
Phone No.	+86-532-86613616
Contact Person	Ms. Huiying Zhao
Email	youjia_zhaohy@sina.com
Date Prepared	May 8, 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	BiuBiu Tampon
Device versions	Regular, Super, and Super Plus
Common name	Unscented Menstrual Tampon
Device Class	II
Classification Number	21 CFR 884.5470
Classification Name	Unscented menstrual tampon
Product code	HEB (Tampon, Menstrual, Unscented)

4. Predicate Device Information

Trade name	Ontex Tampon (Unscented)
510(k) number	K090819

The predicate device has not been subject to a design related recall.

5. Device Description

The BiuBiu tampon is composed of an absorbent pledget (tampon), a withdrawal cord, and an applicator. The pledgets (cleared under K090819) have a cylindrical, bullet-like shape and the applicators have a smooth, rounded tip to ease insertion. The barrel of the applicator has a no-slip grip design to help hold the tampon tightly. Each tampon is individually wrapped and packaged. There are three versions of the BiuBiu tampon with different absorbencies: regular, super and super plus. Each version has a different color applicator. The BiuBiu tampon is provided non-sterile and for single use only.

6. Indications for Use Statement

The BiuBiu tampon is inserted into the vagina and used to absorb menstrual and other vaginal discharge.

7. Substantial Equivalence Discussion

Item	**Subject Device (K190218): BiuBiu Tampon**	**Predicate Device (K090819): Ontex Tampon (Unscented)**	**Comments**
Manufacturer	Qingdao Youjia Hygiene Technology Co., Ltd	Ontex International	None
Common name	Unscented Menstrual Tampon	Unscented Menstrual Tampon	Same
Indications for use	The BiuBiu tampon is inserted into the vagina and used to absorb menstrual and other vaginal discharge.	Ontex Tampon is a tampon that is inserted into the vagina and used to absorb menstrual fluid. The intended use of the organic cotton tampon is the same as all other products that are legally marketed.	Similar
Design	Tampon with cylindrical shape and bullet-like tip. Applicator with smooth and rounded tip.	Tampon with cylindrical shape and bullet-like tip. Applicator with smooth and rounded tip.	Similar

Components	The BiuBiu tampon is composed of an absorbent pledget and an applicator.	The Ontex Tampon consists of an absorbent pledget, with and without an applicator.	Similar. The predicate device comes without an applicator. However, both the subject and predicate device include tampons with applicators.
Specifications	Regular, super, and super plus	Regular, super, and super plus	Same
Overwrap	Individual wrapping	Individual wrapping	Same
Pledget dimensions	**Regular** Length (mm): 42-46 Diameter (mm): 11.8-12.2 Withdrawal cord (mm): 130-160 Syngina absorption (g): 6.0-9.0	**Regular** Length (mm): 42-46 Diameter (mm): 11.8-12.2 Withdrawal cord (mm): 130-160 Syngina absorption (g): 6.0-9.0	Identical
	Super Length (mm): 46-50 Diameter (mm): 12.8-13.2 Withdrawal cord (mm): 130-160 Syngina absorption (g): 9.0-12.0	**Super** Length (mm): 46-50 Diameter (mm): 12.8-13.2 Withdrawal cord (mm): 130-160 Syngina absorption (g): 9.0-12.0	Identical
	Super plus Length (mm): 48-52	**Super plus** Length (mm): 48-52	Identical

	Diameter (mm): 14.8-15.2 Withdrawal cord (mm): 130-160 Syngina absorption (g): 12.0-15.0	Diameter (mm): 14.8-15.2 Withdrawal cord (mm): 130-160 Syngina absorption (g): 12.0-15.0	
Materials	**-Pledget:** 100% organic cotton **-Withdrawal cord:** 100% organic cotton **-Applicator:** Polyethylene and Polypropylene	**-Pledget:** 100% organic cotton **-Withdrawal cord:** 100% organic cotton **-Applicator:** Cardboard	Different. The pledget and cord are identical. However, the subject device utilizes a different material in the applicator.
Applicator Dimensions	**Inner tube length (mm) X Diameter (mm):** Regular: 41.60±0.20 x 9.75±0.15 Super: 41.60±0.20 x 9.75±0.15 Super plus: 41.60±0.20 x 9.75±0.15 **Outer tube length (mm) X Diameter (mm):** Regular: 76.8±0.9 x 14.35±0.15 Super: 77.6±0.9 x 17.15±0.15 Super plus: 77.6±0.9 x 17.60±0.30	**Length with applicator:** 120 – 125 mm **Diameter with applicator:** 15.9 – 16.1 mm	Different. The subject and predicate device have different dimensions.

The subject and predicate device have similar indications for use statements and have the same intended use. The technological characteristics of the subject device are different – the subject device contains different applicator materials and dimensions. The different technological characteristics of the subject device do not raise different types of safety

and effectiveness questions.

8. Non-Clinical Performance Data

The pledget components of the BiuBiu tampon were cleared under K090819, and remain unchanged. Therefore, data on the performance of the pledgets, consistent with the FDA guidance document: *Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s),* was leveraged from K090819 to support the performance of the BiuBiu Tampon pledgets.

The following non-clinical performance tests were performed on the applicator component of the BiuBiu tampon:

Biocompatibility

Biocompatibility testing per ISO 10993-1:2009 and 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."

- Cytotoxicity (ISO 10993-5:2009)
- Vaginal Irritation (ISO 10993-10:2010)
- Skin Sensitization (ISO 10993-10:2010)

The applicator was demonstrated to be non-cytotoxic, non-irritating, and non-sensitizing.

Physical performance testing

The following physical assessments were performed on the BiuBiu tampon applicator per in house methods with predefined acceptance criteria:

- Appearance
- Dimensions
- Compatibility of tampon and applicator
- Applicator integrity
- Applicator expulsion force

9. Conclusion

The results of the performance testing described above demonstrate that the BiuBiu Tampon is as safe and effective as the predicate device and supports a determination of substantial equivalence.