February 13, 2020

Qingdao Youjia Hygiene Technology Co., Ltd
℅ Emma Xing
Official Correspondent
Suzhou Jiuzhen Consulting Company Ltd.
North Building, A1, 218, Xinghu Str., Suzhou Industrial Park
Suzhou, Jiangsu 15123
CHINA

Re: K192557
Trade/Device Name: Youjia unscented tampon with plastic applicators
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: January 9, 2020
Received: January 16, 2020

Dear Emma Xing:

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,

Monica D. Garcia, Ph.D.
Acting Assistant 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)*
K192557

Device Name
Youjia unscented tampon with plastic applicators

Indications for Use *(Describe)*
The Youjia unscented tampon with plastic applicators are 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:

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*"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."*

# 510(k) Summary – K192557

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: February 12, 2020

Manufacturer: Qingdao Youjia Hygiene Technology Co., Ltd.
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Ms. Emma Xing
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Trade Name: Youjia unscented tampon with plastic applicators

Common Name: Unscented Menstrual Tampon

| | |
|---|---|
| Classification Name: | Unscented menstrual tampon |
| Classification Regulation: | 21 CFR 884.5470 |
| Classification Panel: | Obstetrics/Gynecology |
| Device Class: | Class II |
| Classification Product Code: | HEB (Tampon, Menstrual, Unscented) |

Predicate Device:

Trade Name: BiuBiu Tampon
Manufacturer: Qingdao Youjia Hygiene Technology Co., Ltd.
510(k) Clearance: K190218 (May 9, 2019)

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

Device Description:

Youjia unscented tampon with plastic applicators are composed of an absorbent pledget (tampon), a withdrawal cord and an applicator. The pledgets have a cylindrical, bullet-like shape and the applicators have a smooth, rounded tip to ease insertion. These tampons are provided in three absorbencies: regular (6-9g), super, (9-12g), and super plus (12-15g). Each tampon is individually wrapped and packaged.

The Youjia unscented tampon with plastic applicators are provided non-sterile and for single use only.

Indications for Use Statement:

The Youjia unscented tampon with plastic applicators are inserted into the vagina and used to absorb menstrual and other vaginal discharge.

Substantial Equivalence Discussion:

| | Currently Marketed Predicate BiuBiu Tampon (K190218) | Proposed Youjia unscented tampon with plastic applicators | Comment |
|---|---|---|---|
| Manufacturer | Qingdao Youjia Hygiene Technology Co., Ltd. | Qingdao Youjia Hygiene Technology Co., Ltd. | - |
| Regulation name | Unscented menstrual tampon | Unscented menstrual tampon | No difference |

| | | | |
|---|---|---|---|
| Indications for use | The BiuBiu tampon is inserted into the vagina and used to absorb menstrual and other vaginal discharge. | The Youjia unscented tampon with plastic applicators are inserted into the vagina and used to absorb menstrual and other vaginal discharge. | No difference |
| 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. | No difference |
| Components | The BiuBiu tampon is composed of an absorbent pledget and an applicator. | The tampon is composed of an absorbent pledget and an applicator. | No difference |
| Materials | -Pledget: 100% organic cotton.<br>-Withdrawal cord: 100% organic cotton<br>-Applicator with telescope: Polyethylene and Polypropylene | -Pledget: 100% Rayon.<br>-Withdrawal cord: 67% polyester and 33% cotton.<br>-Applicator with telescope: Polyethylene and Polypropylene<br>-Applicator without Telescope: Polyethylene | Different |
| Applicator color | Orange, Green, Yellow | Applicator with telescope: Green, Red, Blue<br><br>Applicator without telescope: white | Different |
| Specifications | Regular, super, and super plus | Regular, super and super plus. | No difference |

| | | | |
|---|---|---|---|
| Applicator Dimensions | Length with applicator: 120 – 125 mm<br>Diameter with applicator: 14.2 – 17.9 mm | Applicator with telescope: Length: 120 – 125 mm<br>Diameter: 14.2 – 17.3 mm<br>Applicator without telescope: Length: 113 – 120 mm<br>Diameter: 14.05 – 17.15 mm | Different |

The Youjia unscented tampon with plastic applicators and predicate devices have similar indications for use statements and have the same intended use. The differences in technological characteristics between the Youjia unscented tampon with plastic applicators and predicate devices do not raise different safety and effectiveness questions.

Summary of Performance Testing:

The sponsor completed performance testing consistent with the FDA guidance document: Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) issued on July 27, 2005. As the subject tampon is identical to the tampons cleared under K122603 (Ontex International), the sponsor leveraged testing on the K122603 tampons to support the performance of the proposed Youjia unscented tampon with plastic applicators.

*Biocompatibility*

Biocompatibility studies were performed in accordance with the FDA guidance "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process" issued in 2016 and the ISO 10993 standards, as follows:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity

The results of these studies demonstrated that the subject device is biocompatible. In addition, biocompatibility data from K190218 was leveraged to support the subject applicator. Extraction testing per USP <661> was completed to evaluate the safety of the colorants used in the applicator.

*Physical performance testing*

The following physical assessments were performed on the applicators per in house

methods with predefined acceptance criteria:

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

The results of these tests demonstrated that the subject device meets its pre-defined acceptance criteria.

Conclusion:

The Youjia unscented tampon with plastic applicators are substantially equivalent to the proposed predicate device.