April 21, 2022

Dong-A Pharmaceutical Co., Ltd.
℅ Joyce Kwon
President
Provision Consulting Group, Inc.
100 N. Barranca St. Suite 700
West Covina, CA 91791

Re: K212277
Trade/Device Name: Tempo Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: March 18, 2022
Received: March 22, 2022

Dear Joyce Kwon:

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,

for Jason R. Roberts, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212277

Device Name
Tempo Tampon

Indications for Use *(Describe)*
The Tempo Tampon is intended for insertion into the vagina for the absorption of menstrual or 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.

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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 – K212277

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Date Prepared
April 15, 2022

Device Information
Trade Name: Tempo Tampon
Common Name: Unscented Menstrual Tampon
Classification Number: 21 CFR 884.5470
Classification Name: Unscented Menstrual Tampon
Product Code: HEB (Tampon, Menstrual, Unscented)
Regulatory Class: Class II

Predicate Devices
Taebong CottonDay Tampon (K182817)

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

Indication for Use
The Tempo Tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.

Device Description
The Tempo Tampon will be offered as a traditional unscented menstrual 100% cotton tampon consisting of an absorbent pledget, a withdrawal cord, and an applicator. The pledget is of the traditional cylindrical, bullet-like shape and the applicator has a standard rounded tip to ease insertion. Each tampon is individually wrapped and packaged in multi-unit containers for retail sale. It will be offered in two absorbances: Regular and Super.

Substantial Equivalent Comparison Chart

		Subject Device		Predicate Device	
Product Name		Tempo Tampon		Taebong CottonDay Tampon	
510(k) Number		K212277		K182817	
Classification Regulation		884.5470		884.5470	
Product Code		HEB		HEB	
Indications for Use		The Tempo Tampon is intended for insertion into the vagina for theabsorption of menstrual or other vaginal discharge.		The CottonDay Tampon is intended for insertion into the vagina for theabsorption of menstrual or other vaginal discharge.	
Sterile?		No		No	
Design		Tampon with cylindrical shape and bullet-like tip. Applicator with smooth, rounded tip.		Tampon with cylindrical shape and bullet-like tip. Applicator with smooth, rounded tip.	
Syngyna Absorbency (gram)		Regular	6.0 – 9.0	Regular	6.0 – 9.0
		Super	9.0 – 12.0	Super	9.0 – 12.0
Pledget Length (mm)		Regular	44-48	Regular	38
		Super	47-51	Super	47
Pledget Diameter (mm)		Regular	13.5	Regular	12
		Super	13.5	Super	12
Applicator Inner Length (mm)		Regular	73 ± 5%	Regular	73 ± 5%
		Super	73 ± 5%	Super	73 ± 5%
Applicator Outer Length (mm)		Regular	74.5 ± 5%	Regular	76.5 ± 5%
		Super	74.5 ± 5%	Super	76.5 ± 5%
Applicator Inner Diameter (mm)		Regular	11.8 ± 5%	Regular	11.8 ± 5%
		Super	11.8 ± 5%	Super	11.8 ± 5%
Applicator Outer Diameter (mm)		Regular	15 ± 5%	Regular	14.1 ± 5%
		Super	15 ± 5%	Super	14.1 ± 5%
Materials	Pledget	100% Cotton		100% Organic Cotton	
	Applicator	Polyethylene		Polyethylene	

The subject device and predicate device have the same design, tampon absorbencies, and applicator material. The subject and predicate device have different pledget and applicator sizes. The predicate device used organic cotton while the subject device does not. The intended use of the subject and predicate devices are identical – absorption of menstrual or other vaginal discharge. The dimensional and material differences between the subject device and predicate device do not raise different questions of safety and effectiveness.

Non-Clinical Test Data

Performance Testing

The following performance characteristics were assessed in accordance with the 2005 FDA guidance document "Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) – Guidance for Industry and FDA Staff."

- Dimensions
- Absorbency range
- Chemical residues
- Withdrawal cord strength
- Fiber shedding
- Tampon integrity

Biocompatibility Testing

Biocompatibility studies were performed in accordance with the 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" issued in 2020 and ISO 10993 standards as follows:

• Cytotoxicity (MEM Elution Test) per ISO 10993-5:2009
• Sensitization (Guinea Pig Maximization Test) per ISO 10993-10:2010
• Irritation per ISO 10993-10:2010
• Acute Systemic Toxicity per ISO 10993-11:2017

Cytotoxicity, sensitization, and irritation testing were performed on the subject applicator and all the above biocompatibility testing was performed on the subject tampons. The results demonstrated the tampon and applicator were non-cytotoxic, non-sensitizers, non-irritating, and that the tampon was not acutely systemically toxic.

Microbiology Testing

Per the 2005 FDA guidance document mentioned above, microbiology testing was conducted to demonstrate that the subject devices do not:

- Enhance the growth of *Staphylococcus aureus*
- Increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1)
- Alter the growth of normal vaginal microflora

Conclusions

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