September 17, 2021

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

Re: K212272
Trade/Device Name: Tempo Natural Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: July 16, 2021
Received: July 20, 2021

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,

Jason Roberts -S

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)*
K212272

Device Name
Tempo Natural Tampon

Indications for Use *(Describe)*
The Tempo Natural 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.

510(k) Summary – K212272

Submitter
Hyunjeong Jang
Dong-A Pharmaceutical Co., Ltd.
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Official Correspondent
Joyce Kwon
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West Covina, CA 91791

Date Prepared
Sept 15, 2021

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

Predicate Devices
Taebong CottonDay Tampon (K182817)

The predicate device has not been subject to any design-related recalls.

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

Device Description
The Tempo Natural Tampon will be offered as a traditional unscented menstrual 100% organic 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. It will be offered in two absorbances: Regular and Super.

Substantial Equivalent Comparison Chart

		Subject Device		Predicate Device (K182817)	
Product Name		Tempo Natural Tampon		Taebong CottonDay Tampon	
Classification Regulation		884.5470		884.5470	
Product Code		HEB		HEB	
Indications for Use		The device is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.		The device is intended for insertion into the vagina for the absorption 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	38	Regular	38
		Super	47	Super	47
Pledget Diameter (mm)		Regular	12	Regular	12
		Super	12	Super	12
Applicator Inner Length (mm)		Regular	73 ± 5%	Regular	73 ± 5%
		Super	73 ± 5%	Super	73 ± 5%
Applicator Outer Length (mm)		Regular	76.5 ± 5%	Regular	76.5 ± 5%
		Super	76.5 ± 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	14.1 ± 5%	Regular	14.1 ± 5%
		Super	14.1 ± 5%	Super	14.1 ± 5%
Materials	Pledget	100% Organic Cotton		100% Organic Cotton	
	Applicator	Polyethylene		Polyethylene	

Basis for Substantial Equivalence

The subject device is identical to the predicate device with the same material composition and dimensional characteristics. The subject and predicate device have the same intended use.

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 2016 and ISO 10993 standards as follows:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2010
- Irritation per ISO 10993-10:2010
- Acute Systemic Toxicity per ISO 10993-11:2006

These tests were performed on the subject tampons and applicators, and the results satisfied the ISO standards requirements.

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 Natural Tampon is as safe and effective as the predicate device and supports a determination of substantial equivalence.