October 22, 2021

Cotton High Tech S.L.
Míriam Carrero
Quality Technician
Colònia La Rabeia, S/N
Balsareny, Barcelona 08660
Spain

Re: K211775
Trade/Device Name: COHITECH Organic Cotton Non-Applicator Cottonlock Tampons
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: September 17, 2021
Received: September 20, 2021

Dear Míriam Carrero:

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)*
K211775

Device Name
COHITECH Organic Cotton Non-Applicator Cottonlock Tampons

Indications for Use *(Describe)*
COHITECH Organic Cotton Non-Applicator Cottonlock Tampons (light, regular, super, and super plus absorbencies) are inserted into the vagina and used to absorb menstrual fluid.

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.

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COHITECH Cotton High Tech S.L.		COHITECH Organic Cotton Non-Applicator Cottonlock Tampons

SECTION 5: 510(k) SUMMARY

510(k) Summary

SUBMITTER NAME: Cotton High Tech S.L.
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Summary Preparation Date: 10/18/2021

DEVICE TRADE NAME: COHITECH Organic Cotton Non-Applicator Cottonlock Tampons
COMMON/USUAL NAME: Menstrual Tampon
REGLATION NUMBER: 21 CFR 884.5470
REGULATION NAME: Unscented Menstrual Tampon
PRODUCT CODE: HEB (Unscented Menstrual Tampon)
REGULATORY CLASS: II

PREDICATE DEVICE
Legally Marketed Equivalent Device

Company	Device name	Code	510k#
Cotton High Tech S.L.	Cohitech Non Applicator Organic Cotton Tampons Cohitech Compact Applicator Organic Cotton Tampons	HEB	K152284

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

DEVICE DESCRIPTION:

The subject device is a conventional unscented menstrual tampon consisting of an organic cotton absorbent pledget (“absorbent core”), completely surrounded by an organic cotton cover (“security veil”) and with an organic cotton string (“withdrawal cord”). These tampons will be provided on four absorbencies: light (6g and under), regular (6-9g), super (9-12g) and super plus (12-15g).

Each organic cotton non-applicator Cottonlock tampon is wrapped in a cellulose paper individual wrapper and packaged in sealed multi-unit containers for retail sale.

COHITECH
Cotton High Tech S.L.

COHITECH Organic Cotton Non-Applicator Cottonlock Tampons

SECTION 5: 510(k) SUMMARY

Device trade name COHITECH Organic Cotton Non-Applicator Cottonlock Tampons could be put into the market with various brands.

Additional information can be found in *Table 5.1.*

INDICATIONS FOR USE:

COHITECH Organic Cotton Non-Applicator Cottonlock Tampons (light, regular, super, and super plus absorbencies) are inserted into the vagina and used to absorb menstrual fluid.

COMPARISON OF INDICATIONS FOR USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Description	**Subject Device**	**Predicate Device**
Device Name	COHITECH Organic Cotton Non-Applicator Cottonlock Tampons	COHITECH Non Applicator Organic Cotton Tampons
Manufacturer/ Applicant	Cotton High Tech S.L.	Cotton High Tech S.L.
K Number	K211775	K152284
Product Code	HEB	HEB
Regulation Number	884.5470	884.5470
Indications for Use	COHITECH Organic Cotton Non-Applicator Cottonlock Tampons (light, regular, super, and super plus absorbencies) are inserted into the vagina and used to absorb menstrual fluid.	Cohitech Non Applicator Organic Cotton Tampon and Cohitech Compact Applicator Organic Cotton Tampon are inserted into the vagina and used to absorb menstrual fluid.
Design	Cylindrical Shape	Cylindrical Shape
Material composition		
Tampon	100% without Chlorine (Cl) bleached organic cotton fibers With smooth nonwoven organic cotton cover (security veil)	100% without Chlorine (Cl) bleached organic cotton fibers With or without smooth nonwoven PE/PET cover
Withdrawal cord	Organic Cotton	Organic Cotton
Packaging	Wrapping foil, cellulose paper	Wrapping foil, polypropylene
Device specifications – LIGHT		
Length	36 – 41 mm	N/A
Diameter	11 – 14 mm	N/A
Absorbency	6 g and under	N/A
Tampon weight	With wrapping: 1.5 g – 2.3 g Without wrapping: 1.3 g – 2.1 g	N/A
Absorbent core weight	0.3g – 1.1 g	N/A

COHITECH
Cotton High Tech S.L.

COHITECH Organic Cotton Non-Applicator Cottonlock Tampons

SECTION 5: 510(k) SUMMARY

Device specifications – REGULAR		
Length	40 – 45 mm	43-46 mm
Diameter	12 – 15 mm	12 - 13mm
Absorbency	6-9 g	6-9 g
Tampon weight	With wrapping: 1.8g – 2.8g Without wrapping: 1.5g – 2.5g	With wrapping: 2.2-3.2g Without wrapping: 2.1-3.1g
Absorbent core weight	0.4g – 1.4 g	1.90 – 2.90 g
Device specifications – SUPER		
Length	48 – 53 mm	48 – 51 mm
Diameter	12 – 15 mm	12 – 13 mm
Absorbency	9-12 g	9-12 g
Tampon weight	With wrapping: 2.6 g – 3.6 g Without wrapping: 2.3 g – 3.3 g	With wrapping: 2.5 g – 3.5 g Without wrapping: 2.4 g – 3.4 g
Absorbent core weight	1.0g – 2.0 g	2.2g – 3.2 g
Device specifications – SUPER PLUS		
Length	50 – 55 mm	48 – 51 mm
Diameter	15 – 18 mm	14 – 15 mm
Absorbency	12-15 g	12 -15 g
Tampon weight	With wrapping: 3.6 g – 4.6 g Without wrapping: 3.3 g – 4.3 g	With wrapping: 3.5 g – 4.5 g Without wrapping: 3.4 g – 4.4 g
Absorbent core weight	2.0 g – 3.0 g	3.2g – 4.2 g

Table 5.1 – Comparison of indications for use and technological characteristics

COHITECH Organic Cotton Non-Applicator Cottonlock Tampons are similar to the predicate device “COHITECH Non Applicator Organic Cotton Tampons” in terms of overall design. Both the predicate and the subject device have the same cylindrical-shaped ribbon of absorbent fibers asymmetrically folded, rolled and compressed and a string (“withdrawal cord”) looped around the rectangular ribbon.

The materials of the pledget (“absorbent core”) and the string (“withdrawal cord”) of both subject and predicate devices are the same (organic cotton) and they both include regular, super, and super plus absorbencies. The subject device includes a light absorbency while the predicate device does not. The difference in absorbency levels does not raise different questions of safety and effectiveness.

The differences in technological characteristics between the subject and the predicate devices include their weight, dimensions, nonwoven (security veil) material and packaging

materials. However, these differences do not raise different questions of safety and effectiveness.

SUMMARY DISCUSSION OF NON-CLINICAL DATA

Biocompatibility

Biocompatibility studies were performed in accordance with the 2020 FDA guidance *Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* and standard *ISO 10993-1*:

- Cytotoxicity (ISO 10993-5:2009)
- Vaginal Irritation (ISO 10993-10:2010)
- Delayed Hypersensitivity (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

The following performance characteristics were assessed in accordance with the Guidance for Industry and FDA Staff - *Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)* issued on July 27, 2005:

- Absorbency (Syngyna testing per 21 CFR 801.430(f)(2))
- Chemical residues
- Tampon integrity
- String strength
- Fiber shedding
- Dimensional analysis
- Preclinical Microbiology

Preclinical Microbiology

Preclinical microbiology was conducted per Guidance for Industry and FDA Staff - *Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)* issued on July 27, 2005 and demonstrate that the subject device in its final, manufactured form, does not:

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

The results of the non-clinical testing were acceptable.

CONCLUSIONS:

The results of the non-clinical testing described above demonstrate that COHITECH Organic Cotton Non-Applicator Cottonlock Tampons are substantially equivalent to the predicate device.