February 25, 2022

Cotton High Tech, S.L.
Anna Garcia Lladó
Regulatory and Product Certification Manager
Colònia La Rabeia, S/N
Balsareny, Barcelona 08660
Spain

Re: K220238
Trade/Device Name: COHITECH Cottonlock Tampons with Reusable Applicator
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: January 25, 2022
Received: January 28, 2022

Dear Anna Garcia Lladó:

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)*
K220238

Device Name
COHITECH Cottonlock Tampons with Reusable Applicator

Indications for Use *(Describe)*
COHITECH Cottonlock Tampons with Reusable Applicator 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.

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510(k) Summary
807.92(c)

SUBMITTER NAME: COTTON HIGH TECH S.L.
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Summary Preparation Date: 02/24/2021

DEVICE TRADE NAME: COHITECH Cottonlock Tampons with Reusable Applicator
COMMON NAME: Unscented Menstrual Tampon
REGULATION NAME: TAMPON, MENSTRUAL, UNSCENTED
REGULATION NUMBER: 21 CFR 884.5470
PRODUCT CODE: HEB (Unscented Menstrual Tampon)
DEVICE CLASS: II

PREDICATE DEVICE **807.92(a)(3)**
Legally Marketed Equivalent Device

Company	Product	510(k)#
Cotton High Tech, S.L.	COHITECH ORGANIC COTTON NON-APPLICATOR COTTONLOCK TAMPONS	K211775

REFERENCE DEVICE

Legally Marketed Reference Device

Company	Product	510(k)#
Cotton High Tech, S.L.	COHITECH REUSABLE TAMPON APPLICATOR	K212479

Neither the predicate or reference device have been subject to a design-related recall.

DEVICE DESCRIPTION:

The subject device is an 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 three absorbencies: regular (6-9g), super (9-12g) and super plus (12-15g).

Each COHITECH Cottonlock tampon is individual wrapped in a cellulose paper along with the reusable applicator in its carrying case and packaged in a sealed multi-unit cardboard containers for retail sale.

The subject device deals with inclusion of a reusable tampon applicator, cleared under K212479, to the packaging of tampons cleared under K211775. The tampons are marketed with the appropriate cleared COHITECH Reusable Tampon Applicator (K212479):
- Size 1 (suitable for regular and super tampons)
- Size 2 (suitable for super and super plus tampons)

The device trade name, COHITECH Cottonlock Tampons with Reusable Applicator, could be put into the market with various brands.

INDICATIONS FOR USE:

COHITECH Cottonlock Tampons with Reusable Applicator are inserted into the vagina and used to absorb menstrual fluid.

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

Device & Predicate Device(s):	K220238	K211775
Trade Name	COHITECH Cottonlock Tampons with Reusable Applicator	COHITECH Organic Cotton Non-Applicator Cottonlock Tampons
Indications for Use	COHITECH Cottonlock Tampons with Reusable Applicator are inserted into the vagina and used to absorb menstrual fluid.	COHITECH Organic Cotton Non-Applicator Cottonlock Tampons are inserted into the vagina and used to absorb menstrual fluid.
Components	Tampon, Applicator (telescoping)	Tampon
Tampon Material	100% organic cotton	100% organic cotton
Withdrawal Cord Material	100% organic cotton	100% organic cotton
Cover Material	100% organic cotton	100% organic cotton
Tampon Absorbency	N/A	Light: 6 g and under
	Regular: 6-9g	Regular: 6-9g
	Super: 9-12g	Super: 9-12g
	Super Plus: 12-15g	Super Plus: 12-15g
Applicator Material	Polyethylene	N/A

Applicator Colors	Super-super plus: Violet Regular-super: Pink	N/A

COHITECH Cottonlock Tampons with Reusable Applicator have the same technological characteristics that the predicate COHITECH Organic Cotton Cottonlock Tampons in regard to materials, manufacturing and specifications, with the exception of the addition of the reusable applicator to insert the tampon. The subject and predicate devices have similar indications for use statements and have the same intended use. The differences do not raise different questions of safety and effectiveness.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

As the subject tampon is identical to the tampons cleared under K211775 and the reusable tampon applicator is identical to the applicators cleared under K212479, the sponsor leveraged testing on the K211775 tampons and K212479 reusable applicators to support the performance of the proposed COHITECH Cottonlock Tampons with Reusable Applicator. To support the modifications to the subject device, the following design verification and validation activities were performed:

- Tampon compatibility testing, as performed in K212479

The sponsor provided a statement certifying that there were no changes to the tampons or applicator from their cleared versions. Therefore, new bench testing (per the 2005 FDA guidance document *Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s*), biocompatibility testing (per the 2020 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"*), or reprocessing testing (per the 2015 FDA guidance document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*) on the tampon or applicator is not necessary to address the device changes in the subject device.

CONCLUSION:

The subject and predicate device have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The results of the non-clinical testing described above demonstrate that the COHITECH Cottonlock Tampons with Reusable Applicator is substantially equivalent to the predicate device.