October 8, 2021

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

Re: K212479
Trade/Device Name: COHITECH Reusable Tampon Applicator
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB, HIL
Dated: August 5, 2021
Received: August 9, 2021

Dear Anna Garcia:

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)*
K212479

Device Name
COHITECH Reusable Tampon Applicator

Indications for Use *(Describe)*
COHITECH Reusable Tampon Applicator is intended to be used to insert a digital menstrual tampon into the vagina.

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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COHITECH
Cotton High Tech S.L.

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510(k) Summary
K212479

SUBMITTER NAME:	Cotton High Tech S.L.
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Summary Preparation Date:	10/04/2021
DEVICE TRADE NAME:	COHITECH Reusable Tampon Applicator
COMMON NAME:	Reusable Tampon Applicator
REGULATION NUMBER:	21 CFR 884.5470
REGULATION NAME:	Unscented Menstrual Tampon
REGULATORY CLASS:	II
PRODUCT CODE:	HEB (unscented menstrual tampon) and HIL (scented-deodorized menstrual tampon)

PREDICATE DEVICE:

Company	Product	510(k)#
THINX INC.	re.t.a™ Reusable Tampon Applicator	K180850

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

DEVICE DESCRIPTION:

The COHITECH Reusable Tampon Applicator is a non-sterile, single user, reusable medical device. It is intended to be sold on its own, without a pre-loaded tampon. The applicator requires the user to load the applicator with a legally marketed digital menstrual tampon. The use-life of the subject applicator is 4 years. The applicator requires the user to clean and disinfect the applicator before initial use, before long-term storage and at the end of the menstrual cycle, as well as to clean the device after each use.

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The device consists of a polyethylene outer tampon housing and inner pusher, a polypropylene storage case, and a carrying case (optional).

This device is available in two sizes, one size for regular and super digital tampons and another for super and super plus digital tampons. The total applicator length is 73.3 ± 0.2 mm for both sizes. The overall applicator diameter (outer housing and inner pusher) is 16 ± 0.1 mm for the regular/super digital tampon applicator and 19 ± 0.1 mm for the super/super plus digital tampon applicator. The applicator weight is 5.4 ± 0.2 for the regular/super tampon applicator and 5.7 ± 0.2 g for the super/super plus tampon applicator. The storage case weight is 7.9 ± 0.1 g and carrying case weight is 26.9 ± 0.1 g

INDICATIONS FOR USE STATEMENT:

COHITECH Reusable Tampon Applicator is intended to be used to insert a digital menstrual tampon into the vagina.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS AND INDICATIONS FOR USE:

The following table compares the technological characteristics and indications for use statement of the subject and the predicate device:

Description	Subject Device	Predicate Device
Device Name	COHITECH Reusable Tampon Applicator	re.t.a™ Reusable Tampon Applicator
Manufacturer / Applicant	Cotton High Tech, S.L.	THINX INC
510(k) Number	K212479	K180850
Product Code	HEB, HIL	HEB, HIL
Regulation Number	884.5470	884.5470
Indication for use	COHITECH Reusable Tampon Applicator is intended to be used to insert a digital menstrual tampon into the vagina.	The re.t.a. ™ reusable tampon applicator is intended to be used to insert a digital menstrual tampon into the vagina.
Usability	Reusable	Reusable
Use-life	4 years	2 years
Tampon compatibility	Digital tampons of various sizes (regular, super, and super plus).	Digital tampons of various sizes
Device Design	Outer tampon housing and inner pusher	Sleeve with slit, pusher and outer cover

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The subject and predicate device have the same intended use – to deliver digital menstrual tampons into the vagina. The subject device differs from the predicate device in technological characteristics. The subject device has a different device design, use-life, and material composition.

The differences in technological characteristics between the subject and predicate device do not raise different questions of safety and effectiveness.

SUMMARY DISCUSSION OF NON-CLINICAL PERFORMANCE DATA

Biocompatibility

The following 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)

The results showed that the subject device was non-cytotoxic, non-irritating, and a non-sensitizer.

Bench Testing

The following performance characteristics were assessed to demonstrate that the proposed subject device met applicable design and performance requirements:

- Device weight
- Physical dimensions
- Functional evaluation, including:
  - Injection force of the inner pusher into the outer tampon housing component
  - Ejection force of the inner pusher out of the outer tampon housing component
  - Tampon compatibility and ejection force testing
- Use-life testing

The results of the non-clinical performance data were acceptable and met the established acceptance criteria.

Reprocessing, Cleaning, and Disinfecting

The cleaning instructions provided for the COHITECH Reusable Tampon Applicator were developed per the recommendations in the 2015 FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and

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Labeling." The COHITECH Reusable Tampon Applicator should be washed with unscented soap after every use and disinfected in 70% isopropyl alcohol after every menstrual cycle.

The COHITECH Reusable Tampon Applicator is not provided sterile and is not intended to be sterilized by users.

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 COHITECH Reusable Tampon Applicator is substantially equivalent to the predicate device.