



October 9, 2025

Cotton High Tech S.L.
Míriam Carrero
Regulatory Manager
Colònia la Rabeia s/n
Balsareny, 08660
SPAIN

Re: K252939
Trade/Device Name: COHITECH ORGANIC COTTON COMPACT
APPLICATOR TAMPONS
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: Class II
Product Code: HEB
Dated: September 15, 2025
Received: September 15, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the Food and Drug Administration (FDA) guidance documents entitled "Deciding When to Submit a 510(k) for

a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

510(k) Number (if known)
K252939

Device Name
COHITECH ORGANIC COTTON COMPACT APPLICATOR TAMPONS

Indications for Use (Describe)
COHITECH ORGANIC COTTON COMPACT APPLICATOR TAMPONS (light, regular, super, and super plus) are inserted into the vagina and used to absorb menstrual fluids.

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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510(k) SUMMARY

510(k) Summary

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Regulatory Affairs Manager

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SUMMARY PREPARATION DATE: October 8, 2025

DEVICE TRADE NAME: COHITECH ORGANIC COTTON
COMPACT APPLICATOR TAMPONS

COMMON NAME: Menstrual tampon

REGULATION NUMBER: 21 CFR 884.5470

REGULATION NAME: Tampon, Menstrual, Unscented

PRODUCT CODE: HEB

Predicate #	Predicate trade name	Product code
K211775	COHITECH ORGANIC COTTON NON- APPLICATOR COTTONLOCK TAMPONS	HEB

DEVICE DESCRIPTION

The device is a conventional unscented menstrual tampon consisting of an organic cotton absorbent pledget ("absorbent core"), surrounded by an organic cotton cover ("security veil"), and an organic cotton string ("withdrawal cord"). It features a compact, polyethylene applicator. The inner and outer tubes slide into each other telescopically, so the inner tube must be retracted before use.

These tampons will be provided in four absorbencies: light (6g and under), regular (6-9g), super (9-12g) and super plus (12-15g). Each organic cotton compact applicator tampon is either individually wrapped with cellulose paper or polypropylene and packaged in sealed multi-unit containers for retail sale. The wrapped device can also be sold in bulk.

Device trade name **COHITECH ORGANIC COTTON COMPACT APPLICATOR TAMPONS** could be put into the market with various brands.



510(k) SUMMARY

INDICATIONS FOR USE

COHITECH ORGANIC COTTON COMPACT APPLICATOR TAMPONS (light, regular, super, and super plus absorbencies) are inserted into the vagina and used to absorb menstrual fluid.

SUMMARY DISCUSSION OF NON-CLINICAL DATA FOR THE TAMPON COMPONENT

The tampons in COHITECH ORGANIC COTTON COMPACT APPLICATOR TAMPONS and COHITECH ORGANIC COTTON NON-APPLICATOR COTTONLOCK TAMPONS (K211775) are the exact same. Therefore, the non-clinical data from COHITECH ORGANIC COTTON NON-APPLICATOR COTTONLOCK TAMPONS (K211775) are leveraged in support of the subject device tampon.

Biocompatibility

Biocompatibility studies were performed on the tampon component in accordance with 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"* 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)

Performance

The following tampon 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 tampon in its final, manufactured form, did not:

COHITECH Cotton High Tech S.L. 	510(k) SUBMISSION	Page 3 of 3 COHITECH ORGANIC COTTON COMPACT APPLICATOR TAMPONS
510(k) SUMMARY		

- 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

SUMMARY DISCUSSION OF NON-CLINICAL DATA FOR THE APPLICATOR COMPONENT

The subject device includes a polyethylene applicator to facilitate its insertion. To support the addition of the polyethylene applicator, the following non-clinical testing was completed:

Biocompatibility

Biocompatibility studies were performed in accordance with 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"* and standard *ISO 10993-1*:

- Cytotoxicity (ISO 10993-5:2009)
- Vaginal Irritation (ISO 10993-23:2021)
- Delayed Hypersensitivity (ISO 10993-10:2021)

Performance

Expulsion force testing was conducted to ensure functionality of the subject device.

CONCLUSIONS:

The results of the non-clinical testing described above demonstrate that **COHITECH ORGANIC COTTON COMPACT APPLICATOR TAMPONS** are substantially equivalent to the predicate device.