March 15, 2019

Cotton High Tech, SL
Anna Garcia Llado
Quality Manager
Colonia La Rabeia, S/N
Balsareny, Barcelona 08660
Spain

Re: K182813
Trade/Device Name: COHITECH Organic Cotton Cardboard Applicator Tampons Light
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: February 12, 2019
Received: February 15, 2019

Dear Anna Garcia Llado:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182813

Device Name

COHITECH Organic Cotton Cardboard Applicator Tampons Light

Indications for Use *(Describe)*

COHITECH Organic cotton cardboard applicator tampons light are unscented menstrual tampons that 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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510(k) Summary – K182813

1. Submitter Information

Applicant: COTTON HIGH TECH S.L.
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2. Correspondent Information

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3. Date prepared:

September 28, 2018

4. Device Information

Device Name:	COHITECH ORGANIC COTTON CARDBOARD APPLICATOR TAMPONS LIGHT
Common Name:	Unscented Menstrual Tampon
Regulation Number:	21 CFR 884.5470
Regulation Name:	Unscented Menstrual Tampon
Regulatory Class:	Class II
Product Code:	HEB (Tampon, Menstrual, Unscented)

5. Predicate Device Information

Maxim menstrual tampons and Organyc menstrual tampons (K091084) manufactured by Cotton High Tech S.L.

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

6. Device Description

The device is a conventional unscented menstrual tampon consisting of an absorbent pledget, a withdrawal cord and an applicator. It will be provided on light absorbency (6g and under). Each tampon is wrapped in an individual wrapper and packaged in sealed multi-unit containers for retail sale.

7. Indications for Use

COHITECH Organic cotton cardboard applicator tampons light are unscented menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

This submission deals with the addition of a new light version to an existing family of tampons (Regular, Super, and Super Plus) that was cleared under K091084

Devices	K182813 (subject device)	K091084 (predicate device)
Intended use	Same as the predicate device	The device is intended to be inserted into the vagina to absorb menstrual fluid
Design (pledget)	Same as the predicate device	Cylindrical shape. Applicator with silky and rounded tip
Absorbency	Light	Regular, Super, Super Plus
Material	Same as the predicate device	100% Organic Cotton

The subject device has the same intended use and technological characteristics, with the exception of changes to the pledget to achieve the lower absorbency, and the applicator to accommodate the smaller tampon size. The differences in technological characteristics do not raise different questions of safety or effectiveness.

9. Summary of Non-Clinical Performance Testing

Performance testing

The following performance characteristics were assessed in accordance with the 2005 FDA guidance "Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)":

- Dimensions
- Absorbency range
- Withdrawal cord strength
- Fiber shedding

A declaration of conformity statement has been provided, which states the verification activities, as required by the risk analysis, for the modification were performed and the results demonstrated that the predetermined acceptance criteria were met. In addition, a statement confirming that the manufacturing facility is also in conformance with the design control requirements, has been provided by the sponsor.

Microbiology testing

The sponsor has relied on prior testing included in K091084 to meet the 2005 FDA guidance requirements for microbiology testing as mentioned above. The sponsor has certified that the device materials are the same and provided acceptable rationales supporting how testing on the larger versions of the device are supportive of the light version of the device.

In addition, microbiological testing data on the subject device has been provided as listed below:

- Total aerobic microbial count: $\leq 2 \times 10^2$ cfu
- Yeast and mold: $\leq 2 \times 10^1$ cfu
- Enterobacteriaceae family: $\leq 10^1$ cfu
- *Escherichia coli*: $\leq 10^1$ cfu
- *Pseudomonas aeruginosa*: Absence in 1g
- *Staphylococcus aureus*: Absence in 1g
- *Candida albicans*: Absence in 25g

Biocompatibility testing

The subject device is made from the same materials used in the prior submission for the larger tampon versions (K091084). Therefore, new biocompatibility testing is not required to support this Special 510(k). A statement certifying that the materials of the new light version of the device are identical to the devices cleared in K091084 was included.

10. Conclusion

The performance data demonstrate that the subject devices are substantially equivalent to the predicate device.