DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 4, 2015

Cotton High Tech S.L.
Anna Garcia
Quality Manager
Colonia La Rabeia s/n
08660 – Balsareny
Barcelona, Spain

Re: K152284
Trade/Device Name: Cohitech Non Applicator Organic Cotton Tampons
Cohitech Compact Applicator Organic Cotton Tampons
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: Class II
Product Code: HEB
Dated: September 3, 2015
Received: September 8, 2015

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152284

Device Name
Cohitech Non Applicator Organic Cotton Tampons
Cohitech Compact Applicator Organic Cotton Tampons

Indications for Use *(Describe)*

Cohitech Non Applicator Organic Cotton Tampons and Cohitech Compact Applicator Organic Cotton Tampons (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.

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510(k) Summary
807.92(c)

SUBMITTER NAME: COTTON HIGH TECH SL
SUBMITTER ADDRESS: Colònia La Rabeia, s/n
08660 Balsareny
BARCELONA
SPAIN

CONTACT: Anna Garcia
Quality Manager
TELEPHONE: + 34 93 839 16 28
FAX: + 34 93 839 19 44
e-mail: agarcia@cohitech.net

Summary Preparation Date: 7/27/2015

DEVICE TRADE NAME: COHITECH NON APPLICATOR ORGANIC COTTON TAMPONS
COHITECH COMPACT APPLICATOR ORGANIC COTTON TAMPONS

COMMON NAME: TAMPON, MENSTRUAL, UNSCENTED
CLASSIFICATION NAME: TAMPON, MENSTRUAL, UNSCENTED
(21 CFR 880.5470, Product Code HEB)
DEVICE CLASS: II

PREDICATE DEVICE
Legally Marketed Equivalent Device

Company	Product	510(k)#
Personal Products Company	O.b. non applicator tampons	K991118
Cotton High Tech S.L.	Cotton menstrual tampons	K091084

DEVICE DESCRIPTION:

The devices are conventional unscented menstrual tampons consisting of an absorbent pledget, with or without polyethylene/polyester cover and a withdrawal cord. These tampons will be provided as three absorbencies: regular, super and super plus.

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

Each compact applicator organic cotton tampon is inserted into a plastic compact applicator and wrapped in an individual wrapper and packaged in sealed multi-unit containers for retail sale.

Device trade names COHITECH NON APPLICATOR ORGANIC COTTON TAMPONS and COHITECH COMPACT APPLICATOR ORGANIC COTTON TAMPONS could be put into the market with various brands. COHITECH NON APPLICATOR ORGANIC COTTON TAMPONS will be marketed with “MAXIM” brand and COMPACT APPLICATOR ORGANIC COTTON TAMPONS will be marketed with “ORGANYC” brand.

INTENDED USE:

Cohitech non applicator organic cotton tampons and Cohitech compact applicator organic cotton tampons (regular, super and super plus absorbencies) are inserted into the vagina and used to absorb menstrual fluid.

TECHNOLOGICAL CHARACTERISTICS:

Non applicator organic cotton tampons are similar to the predicate “O.b. non applicator tampons” in terms of overall design and cover composition (when cover it is present). Both the predicate and the subject device have the same cylindrical-shaped pad of absorbent fibers asymmetrically folded, rolled and compressed; a withdrawal cord looped around the rectangular fiber pad and polyethylene/polyester cover (when it is present).

Non applicator organic cotton tampons are similar to the predicate “Cotton menstrual tampons” in terms of absorbent core and withdrawal cord materials. Both the predicate and the subject device absorbent core and withdrawal cord are made of 100% cotton fibers.

Compact applicator organic cotton tampons are similar to the predicate “O.b. non applicator tampons” in terms of overall design and cover composition (when cover it is present). Both the predicate and the subject device have the same cylindrical-shaped pad of absorbent fibers asymmetrically folded, rolled and compressed; a withdrawal cord looped around the rectangular fiber pad and polyethylene/polyester cover (when it is present).

Compact applicator organic cotton tampons are similar to the predicate “Cotton menstrual tampons” in terms of absorbent core and withdrawal cord materials and how to insert the tampon into the vagina. Both the predicate and the subject device absorbent core and withdrawal cord are made of 100% cotton fibers and are inserted into the vagina with an applicator.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

The non-clinical performance data provided including the following:

- Biocompatibility Testing – cytotoxicity, sensitization, irritation, and acute systemic toxicity
- Syngyna Absorbency Testing
- Fiber Composition
- Withdrawal Cord Strength
- Fiber Shedding
- Expulsion Force
- Tampon Integrity
- Dimensional analysis
- Chemical residues
- Preclinical Microbiology, demonstrating that the tampon does not
    - Enhance the growth of Staphylococcus aureus (S. aureus)
    - Increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1)
    - Alter the growth of the normal vaginal microflora
- Total Microbial Count (TAMC)
- Fungal/Yeast/Mold Limits
- Absence of Pathogenic Organisms (Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, and Candida albicans)

The results of the non-clinical performance data were acceptable.

CONCLUSION:

The COHITECH NON APPLICATOR ORGANIC COTTON TAMPONS and COHITECH COMPACT APPLICATOR ORGANIC COTTON TAMPONS are substantially equivalent to their proposed predicate devices.