MAR 2 1 2013

Section 5: 510(k) Summary

DATE OF PREPARATION: January 28, 2013

COMPANY/OWNER: Naturalena Brands, Inc.
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DEVICE TRADE NAME: Veeda 100% Cotton Menstrual Tampon
COMMON NAME: Unscented Menstrual Tampon
CLASSIFICATION NAME: Tampon, Menstrual, Unscented
REGULATION NUMBER: 21 CFR §884.5470
PRODUCT CODE: HEB
DEVICE CLASS: II

PREDICATE DEVICES: Cotton High Tech 100% Organic Cotton Tampon (K091084)
Cottons 100% Natural Cotton Tampon (K080733)

DEVICE DESCRIPTION: The device will be offered as a traditional unscented menstrual 100% cotton tampon consisting of an absorbent pledget, a withdrawal cord, and an applicator. The pledget is of the traditional cylindrical, bullet-like shape and the applicator has a standard rounded tip to ease insertion. Each tampon is individually wrapped and packaged in multi-unit containers for retail sale. It will be offered in three absorbencies: Regular, Super, and Super Plus.

INTENDED USE: The device is intended to be inserted into the vagina to absorb menstrual fluid.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:
The Naturalena 100% Cotton Tampon demonstrates substantial equivalence to both the Cotton High Tech 100% Organic Cotton Tampon (K091084) and the Cottons 100% Natural Cotton Tampon (K080733). Table 5-1 summarizes the key technological characteristics and features of both the predicates and the new device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2013

Naturalena Brands, Inc.
% Mr. Ned Devine
Sr. Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K130609
Trade/Device Name: Naturalena 100% Cotton Plastic Applicator Tampon
Naturalena 100% Cotton Digital Tampon
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: March 5, 2013
Received: March 11, 2013

Dear Mr. Devine:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Herbert P. Lerner -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

Section 4: Indications for Use Statement

510(k) Number: K130609

Device Name: Naturalena 100% Cotton Plastic Applicator Tampon
Naturalena 100% Cotton Digital Tampon

Indications for Use: The Naturalena 100% Cotton Tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130609