Chapter 1 - 510(k) Summary

FEB 18 2009

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Date Prepared: February 28, 2008

Device Name: Digital & Applicator Menstrual Tampons

Trade Name: Cottons 100% Natural Cotton Tampons

Common Name: Unscented menstrual tampons

Classification Name: Unscented menstrual tampon

Device Class: II

Product code: HEB

CFR Reference: 21 CFR 884.5470

Predicate Devices: Tampax® Tampons, PMN K# 061486

SUMMARY REPORT - continued

Device Description and Intended Use:

Cottons Ltd Digital (non applicator) 100% Cotton Tampons

Absorbencies:
- Regular 6-9 gms
- Super 9-12 gms
- Super Plus 12-15 gms

Cottons Ltd Applicator 100% Cotton Tampons

Absorbencies:
- Regular 6-9 gms
- Super 9-12 gms
- Super Plus 12-15 gms

Component Materials (including additives):
Cottons Ltd 100% Cotton Tampons are constructed from 100% natural cotton which is not chlorine bleached and is chemical free (no additives, no fragrances)

The device is a 100% cotton, conventional unscented menstrual tampon. The device consists of a 100% cotton pledget, a withdrawal cord, with and without an applicator. Three absorbencies are offered as shown above.

The cotton absorbent pledget consists of a pad of 100% cotton compressed into the traditional bullet shape. The absorbent pledget is overwrapped with cellophane. A cotton withdrawal cord is sewn to the pad.

Absorbency ranges – both digital and applicator tampons
- Regular 6-9 gms
- Super 9-12 gms
- Super Plus 12-15 gms

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2009

Cottons Pty., Ltd.
c/o Robert Seiple, RAC
Consultant
Bentley Biomedical Consulting, LLC
3817 Seville Road
DENTON TX 76205-8409

Re: K080733
Trade/Device Name: Cottons Ltd., 100% Cotton Tampons
Regulation Number: 21 CFR §884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: February 11, 2009
Received: February 12, 2009

Dear Mr. Seiple:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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; 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Confidential

Chapter 3 - Indications for Use

510(k) Number (if known): K 080733

Device Name: Cottons Ltd., 100% Cotton Tampons

Indications for Use:

Cottons Ltd, 100% Cotton Tampons are unscented, digital and applicator menstrual tampons for the absorption of menstrual fluid.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080733

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