510(k) Summary of Safety and Effectiveness

Trade Name o.b.® Tampons

Common Name Menstrual tampons

Classification Name Unscented menstrual tampons (21 CFR 884.5470)

Statement This modification of the device is substantially equivalent to legally marketed o.b.® tampons.

Device description The device is a cotton/rayon pledget with a removal string. It is available in various absorbencies.

Intended use This device is intended to be used to vaginally absorb menstrual fluid.

Performance data This device performs equivalently to the predicate device of the same absorbency.

- Syngyna values were the same.

No untoward results were seen in the following tests on either the new material or the finished proposed device:

- Cytotoxicity, Elution Method
- Cytotoxicity, Agarose Overlay Method
- Acute Systemic Toxicity in the Mouse
- Mucosal (Vaginal) Irritation in the Rabbit
- Dermal Irritation and Allergic Contact Sensitization: Human Repeat Insult Patch Test (RIPT)
- Acute Intracutaneous Reactivity in the Rabbit
- TSST-1, Tampon Sac Method

Continued on next page

510(k) Summary of Safety and Effectiveness, Continued

Performance Data (continued)

Clinical Equivalency

There was a randomized, double-blind, two-way crossover study in healthy females comparing the proposed device with that of a commercially available tampon over two menstrual cycles.

The tampons were assessed by vaginal culture and speculum examinations performed at screening and at pre-, mid-, and post menstrual visits, and by vaginal and cervical colposcopy performed at screening and post-menstruation. Subjects also completed a diary detailing tampon use.

There were no clinically significant differences between the test and control products.

Conclusion

The proposed device is substantially equivalent to the legally marketed products in technology, intended use, and preclinical / clinical safety and suitability characteristics.

Contact

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Date

November 4, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2002

McNeil-PPC, Inc.
% Ms. Diana L.B. Uhl
Personal Products Company
Division of McNeil-PPC, Inc.
199 Grandview Road
SKILLMAN NJ 08558

Re: K023789
Trade/Device Name: o.b.® Tampons
Regulation Number: 21 CFR 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: 85 HEB
Dated: November 12, 2002
Received: November 13, 2002

Dear Ms. Uhl:

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 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 510(k) premarket notification. The FDA finding of 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number, if known K023789

Device Name: o.b.® Tampons

Indications for Use:
o.b.® Tampons are to be inserted into the vagina in order to absorb menstrual fluid.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__________ OR Over-the-Counter Use ✓

(signature)
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023789