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Appendices

Appendix A - 510(k) Summary

Device Name	Trade name :o.b.® applicator tampon and non-applicator tampon Classification name: unscented menstrual tampons
Equivalence to legally marketed device	Modified o.b.® applicator tampons and non-applicator tampons are substantially equivalent to the current commercial o.b.® tampons, both applicator and non-applicator versions.
Device description	o.b.® tampons are used to absorb menstrual fluid or other vaginal discharge. These tampons will be available in regular, super and super plus absorbencies, and in applicator and non-applicator versions. o.b.® non-applicator tampons are made of cotton and rayon, a polyethylene/polyester cover, and cotton or rayon string. o.b.® applicator tampons are made of cotton and rayon, a polyethylene/polyester cover, and cotton or rayon string. The applicator consists of a cardboard laminate with a coating.
Intended use	o.b.® tampons are inserted into the vagina to collect menstrual fluid. This is the same intended use as current commercial tampons.
Technological characteristics	The only difference between the modified tampons and the predicate device is the rayon component of the absorbent plug. All other technological characteristics are the same for the modified and the predicate device. There is no impact on the function of the device because of the change in the rayon.

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Performance data Non-clinical testing	Biocompatibility and microbiological testing were conducted on the alternate rayon or on extracts thereof. The results of these tests demonstrate that the modified o.b.® tampon is equivalent to legally marketed tampons. The following tests were conducted: • Cytotoxicity • Vaginal Irritation in Rabbits • Microbiological Testing • Acute Systemic Toxicity • Intracutaneous Toxicity
Performance data Clinical testing	A Repeat Insult Patch Test was conducted to confirm the lack of the potential for human dermal irritation and sensitization.
Conclusion	Results of non-clinical and clinical testing indicate that the safety of modified tampon is comparable to current legally marketed, commercial tampons.
Contact	Submitted by Personal Products Company 199 Grandview Road Skillman, NJ, 08558-9418 Contact person: Ralph A. Petrone Manager, Regulatory Affairs Personal Products Worldwide 908 874 1214
Date	This Summary was prepared on November 11,1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ralph Petrone
Manager, Regulatory Affairs
Personal Products
199 Grandview Road
Skillman, NJ 08558-9418

Re: K974629
o.b.® Tampons
Dated: December 10, 1997
Received: December 12, 1997
Regulatory Class: II
21 CFR 884.5470/Procode: 85 HEB

FEB 10 1998

Dear Mr. Petrone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix C - Indications for Use Statement

510(k) Number (if known) K974629

Device Name: o.b.® Tampons, applicator and non-applicator versions

Indications for Use:

o.b.® Tampons are used to absorb menstrual fluid or other vaginal discharge.

(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 ✓
(per 21 CFR 801.109)

Robert P Sathing
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974629