

JUN 29 1999

K 991118

## 510(k) Summary

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**Device name**

Trade name: o.b.® Tampons  
Classification name: unscented menstrual tampons

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**Device description**

o.b.® non-applicator and applicator Tampons are used to absorb menstrual fluid. The modified tampon will be available in Regular, Super, and Super Plus syngyna absorbency ranges.

o.b.® non-applicator and applicator Tampons are made of commercial cotton and rayon, a polyethylene/polyester cover, and cotton or rayon string.

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**Equivalence to a legally marketed device**

The modified o.b.® Tampon is substantially equivalent to current commercial o.b.® non-applicator and applicator Tampons.

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**Intended use**

The modified o.b.® Tampons are inserted into the vagina to collect menstrual fluid. This is the same intended use as current commercial tampons.

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**Technological characteristics**

The only difference between the modified o.b.® Tampons and the predicate tampons is the substitution of an alternate fiber finish on the rayon and cotton components of the tampon.

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**Biocompat-  
ability**

Biocompatibility and microbiological testing has been conducted on the modified tampons and the fiber finish material. The results of these tests demonstrate that the modified o.b.® Tampon is equivalent to legally marketed tampons. This testing included :

Preclinical Evaluations

- Cytotoxicity
- Microbiological Evaluation
- Acute Systemic Toxicity
- Intracutaneous Toxicity
- Vaginal Irritation
- Ames Mutagenicity
- Chromosome Aberration Assay
- Unscheduled DNA Synthesis

Clinical Evaluations

- Human Sensitization
- Vaginal Microflora Study
- Human Vaginal Irritation Study

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**Conclusion**

Results of preclinical and clinical testing indicate that the safety of the modified tampon is comparable to current legally marketed, commercial tampons.

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**Contact**

Submitted by Personal Products Company  
199 Grandview Road  
Skillman NJ 08558-9418

Contact person: Ralph Petrone  
Manager, Regulatory Affairs  
Personal Products Worldwide  
908 874 1214 (phone)  
908 874 1118 (Fax)

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**Date**

This Summary was prepared on March 3, 1999

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JUN 29 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K991118  
o.b.® Tampons, GML fiber finish, applicator and  
non-applicator versions, unscented  
Dated: March 31, 1999  
Received: April 1, 1999  
Regulatory Class: II  
21 CFR §884.5470/Procode: 85 HEB

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 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). 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 requirements, 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/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting 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

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510(k) Number (if known) K991118

Device Name: o.b.<sup>®</sup> non applicator Tampons.

Indications for Use:

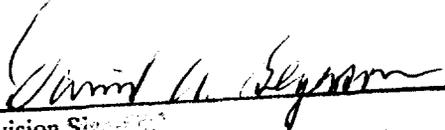
o.b.<sup>®</sup> Tampons are used to absorb menstrual fluid or other vaginal discharge.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR  Over-The-Counter-  
Use \_\_\_\_\_  
(per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Signatory)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K991118

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