AUG 3 1 1999

Pg 1 of 2

Appendices

K990536

510(k) Summary of Safety and Effectiveness (App. A)

Device name	Trade name: o.b.® Tampons Classification name: unscented menstrual tampons
Device description	o.b. ® Non-applicator Tampons are used to absorb menstrual fluid. The modified tampon will be available in the 15-18 gram syngyna absorbency range. o.b.® Non-applicator Tampons are made of commercial cotton and rayon, a polyethylene/polyester cover, and cotton or rayon string.
Equivalence to a legally marketed device	The modified o.b.® Tampon is substantially equivalent to current commercial o.b.® Non-applicator Tampons.
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.
Technological characteristics	The only difference between the modified ob® tampons and the predicate tampons is the absorbency has increased to 15-18 grams absorbency measured by the syngyna test method (21 CFR 801.430). This is accomplished by slight increases in the weight and dimensions of the tampons.

Biocompatability

Biocompatability and microbiological testing has been conducted on tampons made with these commercial materials. The results of these tests demonstrate that the modified ob® Tampon is equivalent to legally marketed tampons. This testing included :

- Microbiological testing
- Clinical Testing

Conclusion

Results of preclinical and clinical testing indicate that the safety of the 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 Petrone
Manager, Regulatory Affairs
Personal Products Worldwide
908 874 1214

Date

This Summary was prepared on February 1, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 1999

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

Re: K990536
o.b.®Ultra Absorbency, non-applicator tampon (15-18 grams)
Dated: June 3,1999
Received: June 4,1999
Regulatory Class: II
21 CFR 884.5435/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.

The agency is currently reviewing the comments that have been received in response to the proposed rule for labeling tampons with this absorbency (*Labeling of Menstrual Tampons; Ranges of Absorbency*; FR January 21, 1999). Please be advised that, depending on the term specified in the final rule, you may have to change your labeling.

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

Appendix C- Indications for Use Statement

510(k) Number (if known) K990536

Device Name: o.b.® non applicator Tampons,
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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990536/S001