

APR 17 1996

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Appendix 8

510(k) Summary

Device Name: Tampax Tampons with Additive

Legally marketed device: Tampax Tampons with Additive are substantially equivalent to legally marketed Tampax OEF tampons.

Device description: Tampax Tampons with Additive are menstrual tampons used to absorb menstrual fluid. Tampax Tampons with Additive will be provided in 4 absorbencies, junior, regular, super and super plus

Tampax Tampons with Additive are made of cotton and/or rayon fibers and overwrap, cotton cord, and an additive. The applicator used in Tampax tampons with Additive is flushable and biodegradable.

Except for the additive, the materials used in Tampax Tampons with Additive are identical to those used in other legally marketed Tampax tampons. This additive has been adequately characterized and evaluated using scientifically valid safety tests.

Intended Use: Tampax Tampons with Additive are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Assessment of performance data

Non-clinical testing: Biocompatibility and microbiological testing of the additive and Tampax Tampons with Additive was conducted. The results of these tests demonstrate that Tampax Tampons with Additive are equivalent in terms of safety and effectiveness to legally marketed tampons. In addition to the review of existing toxicological data, the following tests were conducted related to the safety of Tampax Tampons with Additive:

- Irritation and sensitization testing
- Cytotoxicity testing
- Genotoxicity testing
- In vitro vaginal microflora testing
- Additional microbiological testing

Clinical Testing: A clinical study was done to evaluate the safety of Tampax Tampons with Additive and to compare its safety to its predicates. The study compared Tampax Tampons with Additive to a control tampon during normal menstrual use. Safety was evaluated by comparing the prevalence of product related irritation and other parameters after normal menstrual use.

The study results showed no difference in product related irritation, comfort, or other parameters between Tampax Tampons with Additive and the control product. No significant or unexpected adverse events were observed during the study.

Conclusions: Results of the non-clinical and clinical tests showed that the additive does not alter the safety or effectiveness of the device and that Tampax Tampons with Additive are as safe and as effective , and perform as well as predicate, legally marketed tampons. Further, the results demonstrated that Tampax Tampons with Additive are substantially equivalent to other legally marketed tampons.