

1K971228

510K SUMMARY APR - 9 1997

Device Name: Femtex 100% Cotton Tampons

Legally marketed device: These Femtex 100% Cotton Tampons are substantially equivalent to legally marketed Femtex tampons with applicators.

Device description: Femtex 100% Cotton Tampons are menstrual tampons used to absorb menstrual fluid. Femtex Tampons will be provided with 2 absorbencies, regular, and super.

Femtex 100% Cotton Tampons are made from cotton and, cotton cord and sewing thread.

The material used in Femtex tampons are similar to those used in other legally marketed tampons.

Intended Use: Femtex tampons are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Assessment of Performance Standards: Not Applicable

Non-Clinical Testing: Biocompatibility testing of a cotton tampon which was applicable to the Femtex Tampons was carried out. The results of these tests demonstrate that cotton tampons are equivalent in terms of safety and effectiveness to legally marketed tampons. Standard Syngyna testing confirmed the absorbency of Femtex 100% Cotton Tampons. In addition to the review of existing toxicological data in the public literature, the following tests were conducted relevant to the safety of cotton tampons.

◇ cytotoxicity testing
