

K970232

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510K SUMMARY

Device Name: Femtex 100% Cotton *Gentle Touch* Tampons

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

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

Femtex 100% Cotton *Gentle Touch* Tampons are made from cotton absorbent, cotton cord and cotton sewing thread.

The material used in Femtex 100% Cotton *Gentle Touch* tampons are similar to those used in other legally marketed tampons.

Intended Use: Femtex 100% Cotton *Gentle Touch* 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 the Femtex 100% Cotton *Gentle Touch* Tampons was carried out. The results of these tests demonstrate that Femtex Tampons are equivalent in terms of safety and effectiveness to legally marketed tampons. Standard Syngyna testing confirmed the absorbency of Femtex Tampons. In addition to the review of existing toxicological data in the public literature, the following tests were conducted relevant to the safety of Femtex tampons.

- ◇ irritation testing
- ◇ cytotoxicity testing
- ◇ sensitization testing
- ◇ vaginal irritation testing
