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## 510K SUMMARY

**Device Name:** Femtex *Gentle Touch* Tampons

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

**Device description:** Femtex *Gentle Touch* Tampons are menstrual tampons used to absorb menstrual fluid. Femtex *Gentle Touch* Tampons will be provided with 3 absorbencies, regular, super and super plus.

Femtex *Gentle Touch* Tampons are made from rayon and, cotton cord and sewing thread.

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

**Intended Use:** Femtex *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 *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
- ◇ sensitization testing
- ◇ vaginal irritation testing

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