

FIRST QUALITY HYGIENIC, INC.

CLINTON COUNTY INDUSTRIAL PARK

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510K SUMMARY

K963032

Device Name: Femtex Digital Tampons

Legally marketed device: Femtex Digital Tampons are substantially equivalent to legally marketed Femtex tampons with applicators.

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

Femtex Digital Tampons are made from rayon, polyethylene and polypropylene overwrap and cotton cord. There is no applicator

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

Intended Use: Femtex Digital 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 Digital Tampons was carried out. The results of these tests demonstrate that Femtex Digital Tampons are equivalent in terms of safety and effectiveness to legally marketed tampons. Standard Syngyna testing confirmed the absorbency of Femtex Digital 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 Digital tampons.

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