

**K151470 Opal by Femtex and Private Label Unscented Compact Applicator Tampon, Light Absorbency**Nov 2, 2015  
154 days to decisionK151470 · Product code: **HEB** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k151470/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jun 1, 2015
Decision date	Nov 2, 2015
Days to decision	154 days
Third-party review	Yes
Summary / Statement	Summary
Other names	Opal by Femtex and Private Label Unscented Compact Applicator Tampon, Regular & Super; Opal by Femtex and Private Label Unscented Compact Applicator Tampon, Super Plus; Opal by Femtex and Private Label Unscented Compact Applicator Tampon, Super Absorbency

**APPLICANT**

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Company	<b>First Quality Hygienic, Inc.</b>
Location	Allendale, NJ, US
Contact	Melanie Leibowitz
510(k) history	11 submissions · 11 cleared · 1993-2016

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