

**K161877 Opal by Femtex Pull & Snap and Private Label  
Unscented Compact Applicator Tampon, Regular Opal by  
Femtex Pull & Snap and Private Label Unscented Compact  
Applicator Tampon, Super, Opal by Femtex Pull & Snap and  
Private Label Unscented Compact Applicator Tampon, Super PI**

Aug 5, 2016  
28 days to decision

K161877 · Product code: **HEB** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k161877/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	Jul 8, 2016
Decision date	Aug 5, 2016
Days to decision	28 days
Third-party review	Yes
Summary / Statement	Summary

**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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k161877/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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