

**K132390 INSTINCT**Apr 22, 2014  
264 days to decisionK132390 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k132390/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Aug 1, 2013
Decision date	Apr 22, 2014
Days to decision	264 days
Third-party review	No
Summary / Statement	Statement
Other names	PLAIN, DOTTED, ULTRA THIN

**APPLICANT**

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Company	<b>Profilatex, S.A. DE C.V.</b>
Location	Chalco, MX
Contact	JUAN ERNESTO DE LA PUENTE
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132390/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 7, 2026