

**K103695 PREPEX SYSTEM**Jan 10, 2012  
389 days to decisionK103695 · Product code: **HFX** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k103695/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Circumcision (HFX)
Date received	Dec 17, 2010
Decision date	Jan 10, 2012
Days to decision	389 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Circ Medtech</b>
Location	Chalotte, NC, US
Contact	SHOSHANA FRIEDMAN
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103695/> 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 15, 2026