

**K151095 Circumplast Circumcision Device**Sep 18, 2015  
148 days to decisionK151095 · Product code: **HFX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k151095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Circumcision (HFX)
Date received	Apr 23, 2015
Decision date	Sep 18, 2015
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novadien Healthcare</b>
Location	Mount Lewis, AU
Contact	Milad Melhem
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151095/> 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 4, 2026