

**K112975 CARBONAIID C02 DIFFUSER**Jun 22, 2012  
261 days to decisionK112975 · Product code: **HIF** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k112975/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Oct 5, 2011
Decision date	Jun 22, 2012
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardia Innovation AB</b>
Location	Edina, MN, US
Contact	JEFFREY R SHIDEMAN
510(k) history	2 submissions · 2 cleared · 2006-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112975/> 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 14, 2026