

K052125 CARBONAIID GAS DIFFUSERFeb 8, 2006
187 days to decisionK052125 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k052125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Aug 5, 2005
Decision date	Feb 8, 2006
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052125/> Data sourced from FDA 510(k) public records (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. - Generated June 14, 2026