

**K883283 DISPOSABLE AMNIOTOME**Oct 18, 1988  
75 days to decisionK883283 · Product code: **HGG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k883283/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Abortion Unit, Vacuum (HGG)
Date received	Aug 4, 1988
Decision date	Oct 18, 1988
Days to decision	75 days
Third-party review	No

**APPLICANT**

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Company	<b>Galenica Enterprises, Inc.</b>
Location	Walker, MI, US
Contact	JACQUES R MARCOTTE
510(k) history	5 submissions · 5 cleared · 1984-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883283/>; 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 29, 2026