

**K013281 VERSALAB APM**Apr 18, 2002  
198 days to decisionK013281 · Product code: **HGM** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k013281/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Oct 2, 2001
Decision date	Apr 18, 2002
Days to decision	198 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Nicolet Biomedical</b>
Location	Golden, CO, US
Contact	DAVID W WAGNER
510(k) history	8 submissions · 8 cleared · 1998-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013281/> 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 May 19, 2026