

**K963711 BABY DOPPLEX (3000)**Sep 12, 1997  
361 days to decisionK963711 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k963711/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Sep 16, 1996
Decision date	Sep 12, 1997
Days to decision	361 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Huntleigh Healthcare, Inc.</b>
Location	Eatontown, NJ, US
Contact	AUDREY WITKO
510(k) history	14 submissions · 14 cleared · 1993-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963711/> 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 18, 2026