

**K110612 FM20**Nov 8, 2011  
250 days to decisionK110612 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k110612/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Mar 3, 2011
Decision date	Nov 8, 2011
Days to decision	250 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mediana Co., Ltd.</b>
Location	Flintville, TN, US
Contact	AMY KIM
510(k) history	10 submissions · 10 cleared · 2005-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110612/> 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 18, 2026