

**K123335 SUNRAY FETAL MONITOR**Mar 21, 2013  
146 days to decisionK123335 · Product code: **HGM** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k123335/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Oct 26, 2012
Decision date	Mar 21, 2013
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sunray Medical Apparatus Co., Ltd.</b>
Location	Shenzhen, Guangdong, CN
Contact	SABRINA WEI
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123335/> 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 9, 2026