

**K173042 Fetal & Maternal Monitor: Models F6, F6 Express, F9, F9 Express**Aug 30, 2018  
336 days to decisionK173042 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k173042/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Sep 28, 2017
Decision date	Aug 30, 2018
Days to decision	336 days
Third-party review	No
Summary / Statement	Summary
Other names	Fetal Monitor: Models F2, F3

**APPLICANT**

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Company	<b>Edan Instruments, Inc.</b>
Location	Shenzhen, CN
Contact	Alice Yang
Website	<a href="https://www.edan.com.cn">https://www.edan.com.cn</a>
510(k) history	92 submissions · 92 cleared · 2004-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173042/> 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 30, 2026