

K102140 FETAL MONITORS, MODELS F2 AND F3Jan 13, 2011
168 days to decisionK102140 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k102140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jul 29, 2010
Decision date	Jan 13, 2011
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Edan Instruments, Inc.
Location	Shenzhen, CN
Contact	WILLIAM STERN
Website	https://www.edan.com.cn
510(k) history	92 submissions · 92 cleared · 2004-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102140/> Data sourced from FDA 510(k) public records (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. - Generated June 20, 2026