

K082602 FETAL & MATERNAL MONITOR, MODEL F6, F9Nov 26, 2008
79 days to decisionK082602 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k082602/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Sep 8, 2008
Decision date	Nov 26, 2008
Days to decision	79 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

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