

K100358 CENTRAL MONITORING SYSTEMJan 6, 2011
328 days to decisionK100358 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k100358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Feb 12, 2010
Decision date	Jan 6, 2011
Days to decision	328 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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