

K040903 CADENCE, MODELS 2001 AND 2002Sep 2, 2004
148 days to decisionK040903 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k040903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Apr 7, 2004
Decision date	Sep 2, 2004
Days to decision	148 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/k040903/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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