

K983395 FETALGARD 3000 FETAL MONITORAug 12, 1999
321 days to decisionK983395 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k983395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Sep 25, 1998
Decision date	Aug 12, 1999
Days to decision	321 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Analogic Corp.
Location	Mchenry, IL, US
Contact	STEVEN CLARKE
510(k) history	32 submissions · 32 cleared · 1981-2007

Analogic Corp. is an American multinational corporation specializing in healthcare technology and aviation security. The company, based in McHenry, US, primarily produces imaging equipment including CT scan, digital mammography, and MRI systems for health facilities. Analogic has received FDA 510(k) clearances from total submissions since its first clearance in 1981. The company's regulatory record reflects a strong focus on radiology devices and cardiovascular monitoring systems. The latest FDA 510(k) clearance dates to 2007, establishing this as a historical regulatory ...

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