

K910169 FETALGARD 2000Jul 22, 1991
188 days to decisionK910169 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k910169/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jan 15, 1991
Decision date	Jul 22, 1991
Days to decision	188 days
Third-party review	No

APPLICANT

Company	Analogic Corp.
Location	Mchenry, IL, US
Contact	MARVIN ROSENBAUM
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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