

K950420 FETALGARD 3000 - MODELS IP1, IP2, AP2 AND AP3May 15, 1995
104 days to decisionK950420 · Product code: **HGM** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k950420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Jan 31, 1995
Decision date	May 15, 1995
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Analogic Corp.
Location	Mchenry, IL, US
Contact	JAMES R LEVANI
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 ...
