

K011304 OB-1 FETAL MONITORMay 29, 2001
29 days to decisionK011304 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k011304/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Monitoring, Perinatal (HGM) |
| Date received | Apr 30, 2001 |
| Decision date | May 29, 2001 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Analogic Corp. |
| Location | Mchenry, IL, US |
| Contact | STEVEN A 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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