

K831319 PATIENT MONITOR #404Mar 22, 1984
335 days to decisionK831319 · Product code: **KLK** · Anesthesiology
Source: <https://www.510kdatabase.net/k831319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia (KLK)
Date received	Apr 22, 1983
Decision date	Mar 22, 1984
Days to decision	335 days
Third-party review	No

APPLICANT

Company	Analogic Corp.
Location	Mchenry, IL, US
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 ...