FDA 510(k) Premarket Notification

K001336 DR9000 DIGITAL RADIOGRAPHY X-RAY SYSTEM

CLEARED

Jun 2, 2000
36 days to decision

K001336 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k001336/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Apr 27, 2000
Decision date	Jun 2, 2000
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Analogic Corp.**
Location	Mchenry, IL, US
Contact	ROBERT H FRENCH
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 ...