

K983928 KODAK HOME HEALTH MONITORING SYSTEMFeb 11, 2000
463 days to decisionK983928 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k983928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Nov 5, 1998
Decision date	Feb 11, 2000
Days to decision	463 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Eastman Kodak Company
Location	Mchenry, IL, US
Contact	JUDITH A WALLACE
Website	http://www.kodak.com
510(k) history	238 submissions · 238 cleared · 1977-2006

Eastman Kodak Company is a diversified imaging and materials manufacturer headquartered in McHenry, US. The company has a long history in advanced materials, chemicals, and imaging technologies. Eastman Kodak maintains a significant regulatory history in medical imaging devices. The company received FDA 510(k) clearances from total submissions, with clearances spanning from 1977 to 2006. The company's cleared devices focused primarily on radiology and medical imaging systems, including digital radiography systems, picture archiving and communication systems (PACS), and re...
