

**K020635 KODAK DIRECTVIEW CR 800 SYSTEM, CATALOG#  
1268622**Mar 21, 2002  
22 days to decisionK020635 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k020635/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Feb 27, 2002
Decision date	Mar 21, 2002
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary
Other names	KODAK DIRECTVIEW CR 900 SYSTEM, CATALOG# 1170976

**APPLICANT**

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Company	<b>Eastman Kodak Company</b>
Location	Mchenry, IL, US
Contact	SUSAN PATE
Website	<a href="http://www.kodak.com">http://www.kodak.com</a>
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...