FDA 510(k) Premarket Notification

CLEARED

K021829 MODIFICATION TO KODAK DIRECTVIEW CR 800/900 SYSTEM

Jul 2, 2002
28 days to decision

K021829 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k021829/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Jun 4, 2002
Decision date	Jul 2, 2002
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eastman Kodak Company**
Location	Mchenry, IL, US
Contact	CAROL RYERSON
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...