FDA 510(k) Premarket Notification

CLEARED

K920576 AMERLEX-M HIGH SENSITIVITY UNCONJUGATED ESTRIOL

Mar 23, 1992
42 days to decision

K920576 · Product code: **CGI** · Chemistry
Source: https://www.510kdatabase.net/k920576/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estriol (CGI)
Date received	Feb 10, 1992
Decision date	Mar 23, 1992
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eastman Kodak Company**
Location	Mchenry, IL, US
Contact	YVONNE ADAIR
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...