FDA 510(k) Premarket Notification

K922771 KODAK AMERLEX MAB FT3 ASSAY

CLEARED

Oct 14, 1992
127 days to decision

K922771 · Product code: **CDP** · Chemistry
Source: https://www.510kdatabase.net/k922771/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Triiodothyronine (CDP)
Date received	Jun 9, 1992
Decision date	Oct 14, 1992
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eastman Kodak Company**
Location	Mchenry, IL, US
Contact	BRADFORD M SPRING
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...