

K920247 AMERLITE MAB FT4 ASSAYMar 2, 1992
41 days to decisionK920247 · Product code: **CEC** · Chemistry
Source: <https://www.510kdatabase.net/k920247/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Jan 21, 1992
Decision date	Mar 2, 1992
Days to decision	41 days
Third-party review	No
Summary / Statement	Statement

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...
