

K974597 ADC COMPACT (AGFA DIAGNOSTIC CENTER)Mar 9, 1998
90 days to decisionK974597 · Product code: **KPR** · Radiology
Source: <https://www.510kdatabase.net/k974597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Dec 9, 1997
Decision date	Mar 9, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Corp., Agfa Div.
Location	Ridgefield Park, NJ, US
Contact	MICHAEL SULLIVAN
510(k) history	3 submissions · 3 cleared · 1997-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974597/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026