

K941004 CTS SYSTEMJul 29, 1994
150 days to decisionK941004 · Product code: **IYB** · Radiology
Source: <https://www.510kdatabase.net/k941004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Mount, X-ray, Diagnostic (IYB)
Date received	Mar 1, 1994
Decision date	Jul 29, 1994
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acoma Medical Imaging, Inc.
Location	Wheeling, IL, US
Contact	JAME LAMBRECHT
510(k) history	13 submissions · 13 cleared · 1989-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k941004/> 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