

**K983314 PREMICA CT CONTRAST MEDIA DELIVERY SYSTEM**Feb 19, 1999  
151 days to decisionK983314 · Product code: **IZQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k983314/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector, Contrast Medium, Automatic (IZQ)
Date received	Sep 21, 1998
Decision date	Feb 19, 1999
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nycomed Amersham Imaging</b>
Location	North Attleboro, MA, US
Contact	ROSINA ROBINSON
510(k) history	1 submissions · 1 cleared · 1999-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983314/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 4, 2026