

**K943602 DI-2000**May 12, 1995  
291 days to decisionK943602 · Product code: **IYX** · Radiology  
Source: <https://www.510kdatabase.net/k943602/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Scintillation (gamma) (IYX)
Date received	Jul 25, 1994
Decision date	May 12, 1995
Days to decision	291 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Miles Inc., Agfa Division</b>
Location	Ridgefield Park, NJ, US
Contact	MICHAEL SULLIVAN
510(k) history	2 submissions · 2 cleared · 1994-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943602/> 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 May 20, 2026