

**K944772 MULTIPLE ED1600 SERIES RADIATION SHIELDS**Oct 20, 1994  
23 days to decisionK944772 · Product code: **EAK** · Radiology  
Source: <https://www.510kdatabase.net/k944772/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screen, Leaded, Operator Radiation Protector (EAK)
Date received	Sep 27, 1994
Decision date	Oct 20, 1994
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Image Diagnostics, Inc.</b>
Location	Sterling, MA, US
Contact	REMO J ROSSI
510(k) history	3 submissions · 3 cleared · 1994-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944772/> 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