

**K934478 ALPHA STEREO**Jan 31, 1995  
504 days to decisionK934478 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k934478/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Sep 14, 1993
Decision date	Jan 31, 1995
Days to decision	504 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Instrumentarium Corp.</b>
Location	Tewksbury, MA, US
Contact	RISTO MYNTTINEN
510(k) history	20 submissions · 20 cleared · 1983-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934478/> 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 19, 2026