

K864958 ALPHA II DIAGNOSTIC X-RAYJan 30, 1987
43 days to decisionK864958 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k864958/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Dec 18, 1986
Decision date	Jan 30, 1987
Days to decision	43 days
Third-party review	No

APPLICANT

Company	Ausonics Pty , Ltd.
Location	Mchenry, IL, US
Contact	WILLIAM C NEALON
510(k) history	27 submissions · 26 cleared · 1979-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864958/>; 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 20, 2026