

**K945619 ATHENA HFX**Mar 23, 1995  
128 days to decisionK945619 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k945619/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Nov 15, 1994
Decision date	Mar 23, 1995
Days to decision	128 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Fischer Imaging Corp.</b>
Location	Mchenry, IL, US
Contact	SAMUELLA D EMRICH
510(k) history	69 submissions · 69 cleared · 1981-2004

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945619/> 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 18, 2026