

**K971176 VIEW ARCHIVING STATION**Sep 3, 1997  
156 days to decisionK971176 · Product code: **IZI** · Radiology  
Source: <https://www.510kdatabase.net/k971176/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Mar 31, 1997
Decision date	Sep 3, 1997
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Electromed Intl., Ltd.</b>
Location	Mchenry, IL, US
Contact	JAMES REIDL
510(k) history	23 submissions · 23 cleared · 1981-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971176/> 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