

**K912416 ANGIOGRAPHIC OR FLUOROSCOPIC X-RAY SYSTEM**Aug 28, 1991  
89 days to decisionK912416 · Product code: IZI · Radiology  
Source: <https://www.510kdatabase.net/k912416/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	May 31, 1991
Decision date	Aug 28, 1991
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Xre Corp.</b>
Location	Walker, MI, US
Contact	THOMAS F FLYNN
510(k) history	20 submissions · 20 cleared · 1977-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912416/> 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