FDA 510(k) Premarket Notification

K912416 ANGIOGRAPHIC OR FLUOROSCOPIC X-RAY SYSTEM

CLEARED

Aug 28, 1991
89 days to decision

K912416 · 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	**Xre Corp.**
Location	Walker, MI, US
Contact	THOMAS F FLYNN
510(k) history	20 submissions · 20 cleared · 1977-1997