

K973744 UNICATH SP BI-PLANE (MODEL M269 & M289)Dec 29, 1997
89 days to decisionK973744 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k973744/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Oct 1, 1997
Decision date	Dec 29, 1997
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Xre Corp.
Location	Walker, MI, US
Contact	WAYNE V LOOMER
510(k) history	20 submissions · 20 cleared · 1977-1997

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