FDA 510(k) Premarket Notification

K812217 FLUORO AUTOMATIC BRIGHTNESS SYS

CLEARED

Sep 16, 1981
42 days to decision

K812217 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k812217/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Aug 5, 1981
Decision date	Sep 16, 1981
Days to decision	42 days
Third-party review	No

APPLICANT

Company	**Keystone X-Ray, Inc.**
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1981-1993