FDA 510(k) Premarket Notification

K895546 MODIFIED SPANTRON FRAME FREEZE

CLEARED

Nov 13, 1989
61 days to decision

K895546 · Product code: **JAA** · Radiology
Source: https://www.510kdatabase.net/k895546/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Sep 13, 1989
Decision date	Nov 13, 1989
Days to decision	61 days
Third-party review	No

APPLICANT

Company	**Spantron, Inc.**
Location	Amherst, NY, US
Contact	STEPHEN RUDIN
510(k) history	2 submissions · 2 cleared · 1989-1989