FDA 510(k) Premarket Notification

CLEARED

K920431 OMNITRON NEEDLE APPLICATORS 18 AND 21 GAUGE

May 29, 1992
116 days to decision

K920431 · Product code: **JAQ** · Radiology
Source: https://www.510kdatabase.net/k920431/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Feb 3, 1992
Decision date	May 29, 1992
Days to decision	116 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Omnitron Intl., Inc.**
Location	New Orleans, LA, US
Contact	LISA S JONES
510(k) history	7 submissions · 7 cleared · 1988-1992