FDA 510(k) Premarket Notification

K923130 IR-192 IMPLANT -- MODIFICATION

CLEARED

Sep 21, 1992
88 days to decision

K923130 · Product code: **KXK** · Radiology
Source: https://www.510kdatabase.net/k923130/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Jun 25, 1992
Decision date	Sep 21, 1992
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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