FDA 510(k) Premarket Notification

K901615 PULMOCATH INTRABRONCHIAL CATHETER

CLEARED

Nov 27, 1992
966 days to decision

K901615 · Product code: **JAQ** · Radiology
Source: https://www.510kdatabase.net/k901615/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Apr 6, 1990
Decision date	Nov 27, 1992
Days to decision	966 days
Third-party review	No

APPLICANT

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