FDA 510(k) Premarket Notification

K903216 THE GUIDER CORONARY GUIDING CATHETER

CLEARED

Oct 19, 1990
88 days to decision

K903216 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k903216/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jul 23, 1990
Decision date	Oct 19, 1990
Days to decision	88 days
Third-party review	No

APPLICANT

Company	**Intec Medical, Inc.**
Location	Blue Springs, MO, US
Contact	KENNETH A SPECTOR
510(k) history	17 submissions · 17 cleared · 1980-1991