FDA 510(k) Premarket Notification

K864949 INSTRUCTION CHANGE FOR RIGHT ATRIAL/RAAF CATHETER

CLEARED

Feb 25, 1987
82 days to decision

K864949 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k864949/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Dec 5, 1986
Decision date	Feb 25, 1987
Days to decision	82 days
Third-party review	No

APPLICANT

Company	**Quinton, Inc.**
Location	Mchenry, IL, US
Contact	RANDY WALLS
510(k) history	164 submissions · 160 cleared · 1976-2003