FDA 510(k) Premarket Notification

K931729 I.V. START KIT

CLEARED

Feb 22, 1994
321 days to decision

K931729 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k931729/

SUBMISSION DETAILS

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Apr 7, 1993
Decision date	Feb 22, 1994
Days to decision	321 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Carapace, Inc.**
Location	Mchenry, IL, US
Contact	JERRY W MYERS
510(k) history	22 submissions · 10 cleared · 1979-1994