FDA 510(k) Premarket Notification

CLEARED

K981382 PASV DUAL LUMEN PERIPHERALLY INSERTED MIDLINE CATHETER MODEL NUMBER MIDLINE-NUMEROUS

May 1, 1998
15 days to decision

K981382 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k981382/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Apr 16, 1998
Decision date	May 1, 1998
Days to decision	15 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Catheter Innovations, Inc.**
Location	Salt Lake City, UT, US
Contact	ROGER L RICHINS
510(k) history	8 submissions · 8 cleared · 1998-2002