FDA 510(k) Premarket Notification

K911605 TRACKER UNIBODY, UNIBODY W/SIDE & 25 SIDE HOLES

CLEARED

Jul 9, 1991
90 days to decision

K911605 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k911605/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Apr 10, 1991
Decision date	Jul 9, 1991
Days to decision	90 days
Third-party review	No

APPLICANT

Company	**Target Therapeutics**
Location	Los Angeles, CA, US
Contact	ALEXIS BALL
510(k) history	70 submissions · 70 cleared · 1985-1998