FDA 510(k) Premarket Notification

K905548 PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY GUIDEWIRE

CLEARED

Feb 25, 1991
76 days to decision

K905548 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k905548/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 11, 1990
Decision date	Feb 25, 1991
Days to decision	76 days
Third-party review	No

APPLICANT

Company	**Mallinckrodt Medical**
Location	St Louis, MO, US
Contact	DAVID E BROWN
510(k) history	43 submissions · 42 cleared · 1990-2008