FDA 510(k) Premarket Notification

K935170 CARDIOVASCULAR AND VASCULAR GUIDEWIRE MODIFICATIONS

CLEARED

Mar 31, 1994
155 days to decision

K935170 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k935170/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Oct 27, 1993
Decision date	Mar 31, 1994
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lake Region Mfg., Inc.**
Location	Mchenry, IL, US
Contact	CARL BEAURLINE
510(k) history	42 submissions · 42 cleared · 1977-2010