FDA 510(k) Premarket Notification

K952430 FINESSE GUIDEWIRE CORONARY

CLEARED

Aug 18, 1995
86 days to decision

K952430 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k952430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 24, 1995
Decision date	Aug 18, 1995
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Flexmedics**
Location	Minneapolis, MN, US
Contact	DEBRA K FRITZ
510(k) history	20 submissions · 20 cleared · 1986-1999