FDA 510(k) Premarket Notification

K912878 OPEN ENDED GUIDEWIRE

CLEARED

Sep 11, 1991
72 days to decision

K912878 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k912878/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jul 1, 1991
Decision date	Sep 11, 1991
Days to decision	72 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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