FDA 510(k) Premarket Notification

K000011 MODIFIED HYDROPHILIC COATED GUIDEWIRE

CLEARED

Mar 1, 2000
58 days to decision

K000011 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k000011/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jan 3, 2000
Decision date	Mar 1, 2000
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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