FDA 510(k) Premarket Notification

K003483 MODIFIED HYDROPHILIC COATED GUIDEWIRE (STAINLESS STEEL CORE)

CLEARED

Dec 6, 2000
27 days to decision

K003483 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k003483/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 9, 2000
Decision date	Dec 6, 2000
Days to decision	27 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