FDA 510(k) Premarket Notification

K905639 TORQUE HANDLE DEVICE FOR GUIDEWIRE

CLEARED

Feb 20, 1991
65 days to decision

K905639 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k905639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 17, 1990
Decision date	Feb 20, 1991
Days to decision	65 days
Third-party review	No

APPLICANT

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