FDA 510(k) Premarket Notification

K042370 TORAYGUIDE GUIDEWIRE

CLEARED

Dec 17, 2004
108 days to decision

K042370 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k042370/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 31, 2004
Decision date	Dec 17, 2004
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Toray Industries (America), Inc.**
Location	New York, NY, US
Contact	LISA S JONES
510(k) history	18 submissions · 18 cleared · 1986-2004