FDA 510(k) Premarket Notification

K935998 ENTERPRISE

CLEARED

Nov 17, 1995
702 days to decision

K935998 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k935998/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 15, 1993
Decision date	Nov 17, 1995
Days to decision	702 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Camp Intl., Inc.**
Location	Grand Rapids, MI, US
Contact	KATHLEEN P FOCHTMAN
510(k) history	2 submissions · 2 cleared · 1994-1995