FDA 510(k) Premarket Notification

K833965 8 FRENCH DILATOR 15CM, W/LUER LOCK

CLEARED

Dec 16, 1983
30 days to decision

K833965 · Product code: **DRE** · Cardiovascular
Source: https://www.510kdatabase.net/k833965/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Nov 16, 1983
Decision date	Dec 16, 1983
Days to decision	30 days
Third-party review	No

APPLICANT

Company	**Quinton, Inc.**
Location	Mchenry, IL, US
510(k) history	164 submissions · 160 cleared · 1976-2003