FDA 510(k) Premarket Notification

K832386 PERCLUDER DL OCCLUDING BALLOON

CLEARED

Oct 19, 1983
92 days to decision

K832386 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k832386/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jul 19, 1983
Decision date	Oct 19, 1983
Days to decision	92 days
Third-party review	No

APPLICANT

Company	**Datascope Corp.**
Location	Mchenry, IL, US
510(k) history	136 submissions · 135 cleared · 1976-2019