FDA 510(k) Premarket Notification

K781163 ELECTRODE, DEIP.

CLEARED

Sep 26, 1978
76 days to decision

K781163 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k781163/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Jul 12, 1978
Decision date	Sep 26, 1978
Days to decision	76 days
Third-party review	No

APPLICANT

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