FDA 510(k) Premarket Notification

K810102 INFANT ECG ELECTRODE #60-1029

CLEARED

Jan 29, 1981
13 days to decision

K810102 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k810102/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Jan 16, 1981
Decision date	Jan 29, 1981
Days to decision	13 days
Third-party review	No

APPLICANT

Company	**Aspen Laboratories, Inc.**
Location	Mchenry, IL, US
510(k) history	55 submissions · 55 cleared · 1976-1998