FDA 510(k) Premarket Notification

K813013 GEL ELECTRODE

CLEARED

Nov 27, 1981
31 days to decision

K813013 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k813013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Oct 27, 1981
Decision date	Nov 27, 1981
Days to decision	31 days
Third-party review	No

APPLICANT

Company	**Arndt Automation & Assoc.**
Location	Walker, MI, US
510(k) history	1 submissions · 1 cleared · 1981-1981