FDA 510(k) Premarket Notification

K950478 DISPOSABLE ECG MONITORING ELECTRODE #4570 38X60MM

CLEARED

Nov 6, 1995
276 days to decision

K950478 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k950478/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 3, 1995
Decision date	Nov 6, 1995
Days to decision	276 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Nikomed U.S.A., Inc.**
Location	Belle Mead, NJ, US
Contact	DONALD C EPSTEIN
510(k) history	15 submissions · 15 cleared · 1987-2003