

**K950476 DISPOSABLE ECG MONITORING ELECTRODE #4440
60MM, #4420 40MM**

Sep 6, 1995
215 days to decision

K950476 · Product code: **DRX** · Cardiovascular
Source: <https://www.510kdatabase.net/k950476/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 3, 1995
Decision date	Sep 6, 1995
Days to decision	215 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k950476/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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