K090496 QWIKLEAD REUSABLE ELECTROCARDIOGRAPH ELECTRODE PATCH

CLEARED

Sep 1, 2009
188 days to decision

K090496 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k090496/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 25, 2009
Decision date	Sep 1, 2009
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiac Lead Technologies, Inc.**
Location	Washington, DC, US
Contact	CLAUDIA LEWIS-ENG
510(k) history	1 submissions · 1 cleared · 2009-2009