FDA 510(k) Premarket Notification

K940801 K-KLIP

CLEARED

Aug 3, 1994
162 days to decision

K940801 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k940801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Feb 22, 1994
Decision date	Aug 3, 1994
Days to decision	162 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Katecho, Inc.**
Location	Des Moines, IA, US
Contact	LORNE SCHARNBERG
510(k) history	26 submissions · 25 cleared · 1984-2001