FDA 510(k) Premarket Notification

K894920 SELECTRODE

CLEARED

Oct 3, 1989
62 days to decision

K894920 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k894920/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Aug 2, 1989
Decision date	Oct 3, 1989
Days to decision	62 days
Third-party review	No

APPLICANT

Company	**S & W Medico Teknik**
Location	Walker, MI, US
Contact	POVLSEN
510(k) history	46 submissions · 46 cleared · 1984-1995