FDA 510(k) Premarket Notification

K092389 DISPOSAL ECG ELECTRODES, MODEL EASYRODE

CLEARED

Oct 13, 2009
69 days to decision

K092389 · Product code: **DRX** · Cardiovascular
Source: https://www.510kdatabase.net/k092389/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Aug 5, 2009
Decision date	Oct 13, 2009
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Suzuken Co., Ltd.**
Location	Walker, MI, US
Contact	KOJI KUBO
510(k) history	13 submissions · 13 cleared · 1981-2018