

K092389 DISPOSAL ECG ELECTRODES, MODEL EASYRODEOct 13, 2009
69 days to decisionK092389 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 30, 2026