

**K172068 Kenz Cardico1211**Jun 1, 2018  
329 days to decisionK172068 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k172068/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 7, 2017
Decision date	Jun 1, 2018
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Suzuken Co., Ltd.</b>
Location	Walker, MI, US
Contact	Eiji Yamaguchi
510(k) history	13 submissions · 13 cleared · 1981-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172068/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 30, 2026