FDA 510(k) Premarket Notification

K172068 Kenz Cardico1211

CLEARED

Jun 1, 2018
329 days to decision

K172068 · 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	**Suzuken Co., Ltd.**
Location	Walker, MI, US
Contact	Eiji Yamaguchi
510(k) history	13 submissions · 13 cleared · 1981-2018