FDA 510(k) Premarket Notification

K811949 KENL-ECG-3

CLEARED

Aug 13, 1981
37 days to decision

K811949 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k811949/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jul 7, 1981
Decision date	Aug 13, 1981
Days to decision	37 days
Third-party review	No

APPLICANT

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