K163694 Rooti Rx ECG Event Recorder, Rooti Link APP Software

CLEARED

Nov 7, 2017
314 days to decision

K163694 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k163694/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Dec 28, 2016
Decision date	Nov 7, 2017
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rooti Labs , Ltd.**
Location	Taipei, TW
Contact	Sue Chuang
510(k) history	1 submissions · 1 cleared · 2017-2017