FDA 510(k) Premarket Notification

CLEARED

K202464 Vital Sign Monitoring Sensor (Model :XK300)

Apr 26, 2021
242 days to decision

K202464 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k202464/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Aug 27, 2020
Decision date	Apr 26, 2021
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xandar Kardian, Inc.**
Location	Seoul, KR
Contact	Glen (Jeong Woo) Choi
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Alira Health**
Contact	Brennan Sullivan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov