

K202464 Vital Sign Monitoring Sensor (Model :XK300)Apr 26, 2021
242 days to decisionK202464 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k202464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiometer & 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202464/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026