FDA 510(k) Premarket Notification

CLEARED

K250091 KOROT Blood Pressure Monitor (KOROT P3 Accurate)

Mar 14, 2025
59 days to decision

K250091 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k250091/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jan 14, 2025
Decision date	Mar 14, 2025
Days to decision	59 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Korot Co., Ltd.**
Location	Cheonan, KR
Contact	Muyeol Lee
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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