FDA 510(k) Premarket Notification

K231150 Cardio P1

CLEARED

Nov 9, 2023
202 days to decision

K231150 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k231150/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Apr 21, 2023
Decision date	Nov 9, 2023
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bionet Co., Ltd.**
Location	Wonju, Kwangwon-Do, KR
Contact	Kyungeun Park
510(k) history	11 submissions · 11 cleared · 2005-2023