

K231150 Cardio P1Nov 9, 2023
202 days to decisionK231150 · Product code: **DPS** · CardiovascularSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231150/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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