

**K220535 Cardio10**Nov 15, 2022  
264 days to decisionK220535 · Product code: **DPS** · CardiovascularSource: <https://www.510kdatabase.net/k220535/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Feb 24, 2022
Decision date	Nov 15, 2022
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220535/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026