

K232823 MCG-S (AM1000)Apr 5, 2024
205 days to decisionK232823 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k232823/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Sep 13, 2023
Decision date	Apr 5, 2024
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amcg Co., Ltd.
Location	Seoul, KR
Contact	Soyeon Kim
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232823/> 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 14, 2026