FDA 510(k) Premarket Notification

K232823 MCG-S (AM1000)

CLEARED

Apr 5, 2024
205 days to decision

K232823 · 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