FDA 510(k) Premarket Notification

K250349 Vista CMS

CLEARED

Apr 24, 2026
441 days to decision

K250349 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k250349/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Feb 7, 2025
Decision date	Apr 24, 2026
Days to decision	441 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Draeger Medical Instrument Co., Ltd.**
Location	Shanghai, CN
Contact	Xuguang Miao
510(k) history	3 submissions · 3 cleared · 2025-2026