

K252250 Vista 300/Vista 300 S

Apr 10, 2026
267 days to decision

K252250 · Product code: **MHX** · Cardiovascular
Source: <https://www.510kdatabase.net/k252250/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 17, 2025
Decision date	Apr 10, 2026
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Vista 300 Non-Inv Model A, US (2601064); Vista 300 Invasive Model C, US (2601065); Vista 300 S Non-Inv Model A, US (2602425); Vista 300 S Invasive Model B, US (2602426); Vista 300 S Invasive Model C, US (2602427)

APPLICANT

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