

**K250854 Multi-parameter Patient Monitor (N10)**Dec 17, 2025  
271 days to decisionK250854 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k250854/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Mar 21, 2025
Decision date	Dec 17, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Multi-parameter Patient Monitor (N12); Multi-parameter Patient Monitor (N15); Multi-parameter Patient Monitor (N10MPro); Multi-parameter Patient Monitor (N12MPro); Multi-parameter Patient Monitor (N15MPro)

**APPLICANT**

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Company	<b>Shenzhen Comen Medical Instruments Co.,Ltd</b>
Location	Shenzhen, CN
Contact	Charlotte Lin
510(k) history	5 submissions · 5 cleared · 2018-2025

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