

K211619 Multi-Parameter Patient MonitorDec 29, 2022
582 days to decisionK211619 · Product code: **MHX** · CardiovascularSource: <https://www.510kdatabase.net/k211619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	May 26, 2021
Decision date	Dec 29, 2022
Days to decision	582 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Comen Medical Instruments Co.,Ltd
Location	Shenzhen, CN
Contact	Hongbo Yan
510(k) history	5 submissions · 5 cleared · 2018-2025

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