

K221472 Filter and HME/FilterFeb 8, 2023
264 days to decisionK221472 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k221472/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	May 20, 2022
Decision date	Feb 8, 2023
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Ningbo Huakun Medical Equipment Co., Ltd.
Location	Cixi, CN
Contact	Lei Xi
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Puang Technology Consulting Co., Ltd.
Contact	Julie Chen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221472/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026