

K252643 Iso-Gard Filter StraightMay 15, 2026
267 days to decisionK252643 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k252643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Aug 21, 2025
Decision date	May 15, 2026
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Humid-Vent Filter Compact Angled

APPLICANT

Company	Teleflex Medical Sdn. Bhd.
Location	Kamunting, MY
Contact	Suguneswary Subramaniam
510(k) history	2 submissions · 2 cleared · 2026-2026

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