

K112958 HUMID-VENT HEPASep 21, 2012
352 days to decisionK112958 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k112958/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Oct 5, 2011
Decision date	Sep 21, 2012
Days to decision	352 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflex Medical
Location	Fall River, MA, US
Contact	LIZ PAUL
510(k) history	39 submissions · 39 cleared · 2003-2025

Teleflex Medical is an American medical device company headquartered in Wayne, Pennsylvania, with operations in Fall River, US. The company is a major provider of specialty medical devices for critical care and surgical procedures. Teleflex Medical has received FDA 510(k) clearances from total submissions since 2003. The company maintains active regulatory engagement, with the latest clearance in 2025. Its cleared devices span multiple specialties including anesthesiology, general and plastic surgery, cardiovascular, and vascular access systems. The company's product port...

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