

K211286 Ultipor U55/U55N Breathing Circuit Filter and Heat and Moisture ExchangerNov 16, 2021
203 days to decisionK211286 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k211286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Apr 27, 2021
Decision date	Nov 16, 2021
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pall Corporation
Location	Port Washington, NY, US
Contact	Brian Goetz
Website	http://www.pall.com/
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Randy Prebula

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/k211286/> 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 26, 2026