

**K202459 Bact-Trap Filter, Bact-Trap Mini, Bact-Trap Midi,
Pharma Mini HME/Filter, Bact-HME HME/Filter and Bact-HME
Midi HME/Filter**Sep 26, 2021
395 days to decisionK202459 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k202459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Aug 27, 2020
Decision date	Sep 26, 2021
Days to decision	395 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pharma System AB
Location	Knivsta, SE
Contact	Viljar Salumaa
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	MEDlcept, Inc.
Contact	Scott Blood

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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