

K190022 SafeBreath Filter MouthpieceSep 25, 2019
264 days to decisionK190022 · Product code: **CAH** · General Hospital
Source: <https://www.510kdatabase.net/k190022/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Bacterial, Breathing-circuit (CAH)
Date received	Jan 4, 2019
Decision date	Sep 25, 2019
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MD Diagnostics Limited
Location	Maidstone, GB
Contact	Glen Hillsley
510(k) history	2 submissions · 2 cleared · 2018-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190022/> 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 June 29, 2026