

K220145 Monaghan medical filtered mouthpiece kitAug 24, 2023
582 days to decisionK220145 · Product code: **CAF** · AnesthesiologySource: <https://www.510kdatabase.net/k220145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jan 19, 2022
Decision date	Aug 24, 2023
Days to decision	582 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Monaghan Medical Corporation
Location	Plattsburgh, NY, US
Contact	Cari J Reil
510(k) history	2 submissions · 2 cleared · 2011-2023

REGULATORY CONSULTANT

Consulting firm	Aztech Regulatory & Quality, LLC
Contact	Joseph Azary

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

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