

K193411 O2asis Personal Oxygen HumidifierNov 12, 2020
339 days to decisionK193411 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k193411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Dec 9, 2019
Decision date	Nov 12, 2020
Days to decision	339 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Perma Pure, LLC
Location	Lakewood, NJ, US
Contact	Sidra Hankins
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Perma Pure, LLC C/O Promedic, LLC
Contact	Paul Dryden

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193411/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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