

K241268 Thermalite Heated CPAP Tube (CTUBH06H15DS-2, CTUBH15-DS)Aug 2, 2024
88 days to decisionK241268 · Product code: **BZE** · Anesthesiology
Source: <https://www.510kdatabase.net/k241268/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heater, Breathing System W/wo Controller (not Humidifier Or Nebulizer (BZE)
Date received	May 6, 2024
Decision date	Aug 2, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exceleron Medical
Location	St. Paul, MN, US
Contact	Keith Roberts
510(k) history	2 submissions · 2 cleared · 2014-2024

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

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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