

K201418 Sunset Heated CPAP TubeJan 29, 2021
245 days to decisionK201418 · Product code: **BZE** · Anesthesiology
Source: <https://www.510kdatabase.net/k201418/>**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 29, 2020
Decision date	Jan 29, 2021
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sunset Healthcare Solutions, Inc.
Location	Chicago, IL, US
Contact	N. (Nazree) Williams
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Speed TO Market, Inc.
Contact	Thomas Kroenke

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

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