

K220854 TrachCuff Cuff ControllerApr 14, 2023
387 days to decisionK220854 · Product code: **BSK** · Anesthesiology
Source: <https://www.510kdatabase.net/k220854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Tracheal Tube, Inflatable (BSK)
Date received	Mar 23, 2022
Decision date	Apr 14, 2023
Days to decision	387 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aw Technologies Aps
Location	Norresundby, DK
Contact	Adam Hansen
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Imagenix, Inc.
Contact	Stephen Gorski

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

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