

K221477 AG100sDec 29, 2022
220 days to decisionK221477 · Product code: **BSK** · Anesthesiology
Source: <https://www.510kdatabase.net/k221477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Tracheal Tube, Inflatable (BSK)
Date received	May 23, 2022
Decision date	Dec 29, 2022
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hospitech Respiration , Ltd.
Location	Binyamina, IL
Contact	Yoel Bergman
510(k) history	6 submissions · 6 cleared · 2010-2022

REGULATORY CONSULTANT

Consulting firm	ProMedoss, Inc.
Contact	Bosmat Friedman

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/k221477/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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