

K192611 CuffixAug 13, 2020
328 days to decisionK192611 · Product code: **BSK** · Anesthesiology
Source: <https://www.510kdatabase.net/k192611/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Tracheal Tube, Inflatable (BSK)
Date received	Sep 20, 2019
Decision date	Aug 13, 2020
Days to decision	328 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biovo Technologies , Ltd.
Location	Rosh Haayin, IL
Contact	Barbara Sokoletsky
510(k) history	1 submissions · 1 cleared · 2020-2020

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/k192611/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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