FDA 510(k) Premarket Notification

K192611 Cuffix

CLEARED

Aug 13, 2020
328 days to decision

K192611 · 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