

K182548 Accucuff Cuff Pressure IndicatorJan 25, 2019
130 days to decisionK182548 · Product code: **BSK** · Anesthesiology
Source: <https://www.510kdatabase.net/k182548/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Tracheal Tube, Inflatable (BSK)
Date received	Sep 17, 2018
Decision date	Jan 25, 2019
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tianjin Medis Medical Device Co., Ltd.
Location	Tianjin City, CN
Contact	Yongzhi Wu
510(k) history	3 submissions · 3 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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

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