

K232580 Disposable Endobronchial Blocker TubeDec 14, 2023
111 days to decisionK232580 · Product code: **CBI** · Anesthesiology
Source: <https://www.510kdatabase.net/k232580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal/bronchial, Differential Ventilation (w/wo Connector) (CBI)
Date received	Aug 25, 2023
Decision date	Dec 14, 2023
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Insighters Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Bonnie Fang
510(k) history	3 submissions · 3 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232580/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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