

**K242793 Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B12A 4.6/2.0**May 28, 2025  
254 days to decisionK242793 · Product code: **EOQ** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k242793/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Sep 16, 2024
Decision date	May 28, 2025
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B22A 5.5 /2.6; Insighters™ Single-use Bronchoscope/Insight Bimodel-Integral iS-B26A 6.0/3.0; Insighters™ Insight Workstation iS-PF1.

**APPLICANT**

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

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