

K251478 ClearTip TBNA TypeApr 16, 2026
338 days to decisionK251478 · Product code: **KTI** · Anesthesiology
Source: <https://www.510kdatabase.net/k251478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	May 13, 2025
Decision date	Apr 16, 2026
Days to decision	338 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Finemedix Co., Ltd.
Location	Daegu, KR
Contact	Young-Hun Do
510(k) history	11 submissions · 11 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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