

**K253001 KT Airway Clearance Device II (KT-3)**Jun 16, 2026  
270 days to decisionK253001 · Product code: **NHJ** · Anesthesiology  
Source: <https://www.510kdatabase.net/k253001/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Positive Pressure Breathing, Intermittent (NHJ)
Date received	Sep 19, 2025
Decision date	Jun 16, 2026
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary
Other names	KT Airway Clearance Device II (KT-5)

**APPLICANT**

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Company	<b>Hunan Ruijiong Biotech Co., Ltd.</b>
Location	Xiangtan, CN
Contact	Zen Koo
510(k) history	1 submissions · 1 cleared · 2026-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253001/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated July 11, 2026