

**K182739 Endotracheal Tube with Evacuation Lumen**Dec 11, 2019  
439 days to decisionK182739 · Product code: **BTR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k182739/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	Sep 28, 2018
Decision date	Dec 11, 2019
Days to decision	439 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Well Lead Medical Co., Ltd.</b>
Location	Apollo Beach, FL, US
Contact	Huang Kaigen
510(k) history	17 submissions · 17 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182739/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026