

K211543 Wei Nasal Jet TubeJul 21, 2022
428 days to decisionK211543 · Product code: **BTR** · Anesthesiology
Source: <https://www.510kdatabase.net/k211543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tracheal (w/wo Connector) (BTR)
Date received	May 19, 2021
Decision date	Jul 21, 2022
Days to decision	428 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Well Lead Medical Co., Ltd.
Location	Apollo Beach, FL, US
Contact	Caroline Gong
510(k) history	17 submissions · 17 cleared · 2009-2025

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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

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