

K211894 TrachealatorNov 24, 2021
156 days to decisionK211894 · Product code: **KTI** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k211894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Jun 21, 2021
Decision date	Nov 24, 2021
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Disa Medinotec
Location	Johannesburg, ZA
Contact	Michelle Nieuwoudt
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group, Inc.
Contact	Matthew Krueger

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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