

K203362 TRACOE varioAug 5, 2021
262 days to decisionK203362 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k203362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Nov 16, 2020
Decision date	Aug 5, 2021
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tracoe Medical GmbH
Location	D 6367 Karben 2, DE
Contact	Katharina Schrick
510(k) history	8 submissions · 8 cleared · 1978-2021

REGULATORY CONSULTANT

Consulting firm	Capamed, Inc.
Contact	Lu Anne Bauer

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

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