

**K043160 TRACOE PHON ASSIST I - SPEAKING VALVES,
REFERENCE MODELS: PHON ASSIST I-650-T/TO AND 650-S/SO**Feb 18, 2005
95 days to decisionK043160 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k043160/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Nov 15, 2004
Decision date	Feb 18, 2005
Days to decision	95 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043160/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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