

K152778 TRACOE Cuff Pressure MonitorDec 21, 2016
453 days to decisionK152778 · Product code: **BSK** · Anesthesiology
Source: <https://www.510kdatabase.net/k152778/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Tracheal Tube, Inflatable (BSK)
Date received	Sep 25, 2015
Decision date	Dec 21, 2016
Days to decision	453 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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