

K180474 TNI softFlow 50Oct 18, 2018
238 days to decisionK180474 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k180474/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Feb 22, 2018
Decision date	Oct 18, 2018
Days to decision	238 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tni Medical AG
Location	Wuerzburg, DE
Contact	Joseph P. McMenamin
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	DAVE YUNGVIRT

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

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