

K190824 Airway Gas Sampling Set, disposable, Adult/Pediatric, TPE, 3m/10ft, Airway Gas Sampling Set, disposable, Adult/Pediatric, TPE, 2m/7ft, Airway Gas Sampling Set, disposable, Infant, TPE, 2m/7ft, Airway Adapter with Luer Connector, Adult/PediatricDec 18, 2019
261 days to decisionK190824 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k190824/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Apr 1, 2019
Decision date	Dec 18, 2019
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bluepoint Medical GmbH & Co. KG
Location	Selmsdorf, DE
Contact	Bernd Lindner
510(k) history	2 submissions · 2 cleared · 2017-2019

REGULATORY CONSULTANT

Consulting firm	Imagenix, Inc.
Contact	Stephen Gorski

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190824/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026