

K181424 PeDIASep 25, 2018
117 days to decisionK181424 · Product code: **BTC** · Anesthesiology
Source: <https://www.510kdatabase.net/k181424/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bag, Reservoir (BTC)
Date received	May 31, 2018
Decision date	Sep 25, 2018
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pedia, LLC
Location	Fairfax, VA, US
Contact	Diane Miller
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Ultra Life Science Solutions, Inc.
Contact	Chris Henza

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/k181424/> 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 July 5, 2026