

K123957 PNEUPAC PARAPAC PLUSSep 16, 2013
269 days to decisionK123957 · Product code: **BTL** · Anesthesiology
Source: <https://www.510kdatabase.net/k123957/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Emergency, Powered (resuscitator) (BTL) |
| Date received | Dec 21, 2012 |
| Decision date | Sep 16, 2013 |
| Days to decision | 269 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Smiths Medical International , Ltd. |
| Location | Waukesha, WI, US |
| Contact | LORI BERENDS |
| 510(k) history | 3 submissions · 3 cleared · 2005-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123957/> 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 May 24, 2026