

**K951043 AIR-SOFT-DISPOSABLE,  
ANESTHESIA/RESPIRATORY FACE MASK**Jun 7, 1995  
92 days to decisionK951043 · Product code: **BSJ** · Anesthesiology  
Source: <https://www.510kdatabase.net/k951043/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Gas, Anesthetic (BSJ)
Date received	Mar 7, 1995
Decision date	Jun 7, 1995
Days to decision	92 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Promedic, Inc.</b>
Location	Indianapolis, IN, US
Contact	PAUL E DRYDEN
510(k) history	16 submissions · 14 cleared · 1995-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951043/> 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 25, 2026