

**K060404 AG-PLUS, MODEL 91210**Jun 22, 2006  
127 days to decisionK060404 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k060404/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Feb 15, 2006
Decision date	Jun 22, 2006
Days to decision	127 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Medel S.P.A.</b>
Location	Cary, NC, US
Contact	TERRENCE O' BRIEN
510(k) history	4 submissions · 4 cleared · 2006-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060404/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026