FDA 510(k) Premarket Notification

K060404 AG-PLUS, MODEL 91210

CLEARED

Jun 22, 2006
127 days to decision

K060404 · 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	**Medel S.P.A.**
Location	Cary, NC, US
Contact	TERRENCE O'BRIEN
510(k) history	4 submissions · 4 cleared · 2006-2009