

K070498 HYPER SALApr 26, 2007
65 days to decisionK070498 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k070498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Feb 20, 2007
Decision date	Apr 26, 2007
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pari Innovative Manufacturers, Inc.
Location	Midlothian, VA, US
Contact	PAUL DRYDEN
510(k) history	10 submissions · 10 cleared · 2002-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070498/> 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