FDA 510(k) Premarket Notification

K072019 AKITA2 APIXNEB

CLEARED

Nov 5, 2007
105 days to decision

K072019 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k072019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jul 23, 2007
Decision date	Nov 5, 2007
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Activaero America, Inc.**
Location	Bonita Springs, FL, US
Contact	PAUL DRYDEN
510(k) history	3 submissions · 3 cleared · 2007-2009