FDA 510(k) Premarket Notification

K080100 WATCHHALER

CLEARED

Jun 30, 2008
168 days to decision

K080100 · Product code: **NVP** · Anesthesiology
Source: https://www.510kdatabase.net/k080100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holding Chambers, Direct Patient Interface (NVP)
Date received	Jan 14, 2008
Decision date	Jun 30, 2008
Days to decision	168 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