

**K080100 WATCHHALER**Jun 30, 2008  
168 days to decisionK080100 · Product code: **NVP** · Anesthesiology  
Source: <https://www.510kdatabase.net/k080100/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080100/> 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