

**K101136 FISIO CHAMBER SPACE**Jan 28, 2011  
281 days to decisionK101136 · Product code: **NVP** · Anesthesiology  
Source: <https://www.510kdatabase.net/k101136/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holding Chambers, Direct Patient Interface (NVP)
Date received	Apr 22, 2010
Decision date	Jan 28, 2011
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Koo (Shanghai) Industries Co., Ltd.</b>
Location	Bonita Springs, FL, US
Contact	PAUL DRYDEN
510(k) history	2 submissions · 2 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101136/> 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