

**K133105 BREEZE NEBULIZER (NBR-10X)**Jun 24, 2014  
267 days to decisionK133105 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k133105/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Sep 30, 2013
Decision date	Jun 24, 2014
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Digio2 International Co., Ltd.</b>
Location	Flagstaff, AZ, US
Contact	MICHAEL LEE
510(k) history	3 submissions · 3 cleared · 2009-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133105/> 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