

**K081738 ULTRASONIC NEBULIZER SYSTEM, MODEL HL100**Sep 17, 2008  
90 days to decisionK081738 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k081738/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jun 19, 2008
Decision date	Sep 17, 2008
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Health &amp; Life Co., Ltd.</b>
Location	Taipei Hsien, TW
Contact	SAMUEL PIPER
510(k) history	60 submissions · 60 cleared · 1999-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081738/> 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