

**K864466 OMRON ULTRASONIC NEBULIZER MODEL NE-U05**Mar 26, 1987  
134 days to decisionK864466 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k864466/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 12, 1986
Decision date	Mar 26, 1987
Days to decision	134 days
Third-party review	No

**APPLICANT**

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Company	<b>Omron Tateisi Electronics Co.</b>
Location	Tokyo, 105 Japan, JP
Contact	HISA
510(k) history	7 submissions · 7 cleared · 1985-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864466/>; 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 27, 2026