

**K972371 ICEL ULTRASONIC NEBULIZER MODELS PU 12000  
AIR AND PU 12300 AIR**

Aug 19, 1997  
55 days to decision

K972371 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k972371/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jun 25, 1997
Decision date	Aug 19, 1997
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brasamerica Medical Equipment, Inc.</b>
Location	Great Neck,, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	2 submissions · 2 cleared · 1997-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k972371/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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