

**K850711 INHALATION THERAPY NEBULIZER DEVICE**Jun 5, 1985  
103 days to decisionK850711 · Product code: **KFZ** · AnesthesiologySource: <https://www.510kdatabase.net/k850711/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Non-direct Patient Interface (home-use) (KFZ)
Date received	Feb 22, 1985
Decision date	Jun 5, 1985
Days to decision	103 days
Third-party review	No

**APPLICANT**

---

Company	<b>Med USA</b>
Location	Waltham, MA, US
Contact	JAMES R RUNDELL
510(k) history	5 submissions · 5 cleared · 1985-1990

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850711/>, 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