

**K061071 V-808 ATOM TRANSCAPSULE**Aug 29, 2006  
134 days to decisionK061071 · Product code: **FPL** · General HospitalSource: <https://www.510kdatabase.net/k061071/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal Transport (FPL)
Date received	Apr 17, 2006
Decision date	Aug 29, 2006
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Atom Medical, Inc.</b>
Location	Tokoyo, Bunkyo-Ku, JP
Contact	MARY STANIEWICZ
510(k) history	3 submissions · 3 cleared · 2006-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061071/> 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 June 29, 2026