

**K980886 BABYTHERM 8000 LDR**May 29, 1998  
81 days to decisionK980886 · Product code: **FMZ** · General Hospital  
Source: <https://www.510kdatabase.net/k980886/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Mar 9, 1998
Decision date	May 29, 1998
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Draeger Medical, Inc.</b>
Location	Mchenry, IL, US
Contact	JAMES J BRENNAN
510(k) history	78 submissions · 77 cleared · 1977-2004

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980886/> 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 25, 2026