

**K082367 INFANT SLEEP BEANIE**Jun 12, 2009  
298 days to decisionK082367 · Product code: **FRP** · General Hospital  
Source: <https://www.510kdatabase.net/k082367/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holder, Infant Position (FRP)
Date received	Aug 18, 2008
Decision date	Jun 12, 2009
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Life Innovations, LLC</b>
Location	Wellington, CO, US
Contact	JANE SCOTT
510(k) history	1 submissions · 1 cleared · 2009-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082367/> 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 22, 2026