

**K943017 NEONATAL RESTRAINT AND COMFORT SYSTEMS**Jan 19, 1995  
209 days to decisionK943017 · Product code: **FRP** · General Hospital  
Source: <https://www.510kdatabase.net/k943017/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holder, Infant Position (FRP)
Date received	Jun 24, 1994
Decision date	Jan 19, 1995
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>K.Bowmed, Inc.</b>
Location	North Wilkesboro, NC, US
Contact	KAROLEN C BOWMAN
510(k) history	1 submissions · 1 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943017/> 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 July 6, 2026