

**K845002 CUDDLE HEART -AUDITORY/VIBRATION DEVICE**Apr 23, 1986  
483 days to decisionK845002 · Product code: **FMS** · General Hospital  
Source: <https://www.510kdatabase.net/k845002/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bed, Pediatric Open Hospital (FMS)
Date received	Dec 26, 1984
Decision date	Apr 23, 1986
Days to decision	483 days
Third-party review	No

**APPLICANT**

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Company	<b>International Purchasing Services</b>
Location	Newbury Park, CA, US
Contact	IAN J MCGUGAN
510(k) history	3 submissions · 3 cleared · 1986-1986

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k845002/>; 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 9, 2026