

**K863494 NEONATAL PHYSIOLOGICAL MONITOR MODEL PM  
20**Dec 22, 1986  
104 days to decisionK863494 · Product code: **DRT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k863494/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Sep 9, 1986
Decision date	Dec 22, 1986
Days to decision	104 days
Third-party review	No

**APPLICANT**

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Company	<b>Advantage Medical Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	ANTHONY CALDERONI
510(k) history	17 submissions · 16 cleared · 1980-1987

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k863494/>; 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 27, 2026