

**K043132 UNIVERSAL XACTTRACE**Dec 21, 2004  
39 days to decisionK043132 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k043132/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Nov 12, 2004
Decision date	Dec 21, 2004
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medcare Flaga</b>
Location	Battle Creek, MI, US
Contact	KOLBRUN E OTTOSDOTTIR
510(k) history	4 submissions · 4 cleared · 2003-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043132/> 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