

**K910421 SATURATION/HEMATOCRIT MONITOR SYSTEM**Oct 15, 1991  
258 days to decisionK910421 · Product code: **DRY** · CardiovascularSource: <https://www.510kdatabase.net/k910421/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Blood-gas, On-line, Cardiopulmonary Bypass (DRY)
Date received	Jan 30, 1991
Decision date	Oct 15, 1991
Days to decision	258 days
Third-party review	No

**APPLICANT**

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Company	<b>Medtronic Vascular</b>
Location	Walker, MI, US
Contact	NORMA LOWE
510(k) history	475 submissions · 453 cleared · 1977-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k910421/>, 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 18, 2026