

**K212529 Hypotension Decision Assist Model HDA-OR2**Nov 23, 2021  
104 days to decisionK212529 · Product code: **DXG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k212529/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Aug 11, 2021
Decision date	Nov 23, 2021
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Directed Systems, Ltd.</b>
Location	Cambridge, GB
Contact	Mark S. Leaning
510(k) history	2 submissions · 2 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212529/> 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 24, 2026