

**K032997 MODIFICATION TO: HORIZON 9000WS**Oct 15, 2003  
20 days to decisionK032997 · Product code: **DXG** · CardiovascularSource: <https://www.510kdatabase.net/k032997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Sep 25, 2003
Decision date	Oct 15, 2003
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mennen Medical , Ltd.</b>
Location	Rehovot, IL
Contact	EREZ NIMROD
510(k) history	21 submissions · 21 cleared · 2000-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032997/> 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