

**K151013 Vitaphone Tele ECG Loop Recorder**Apr 30, 2015  
15 days to decisionK151013 · Product code: **DXH** · CardiovascularSource: <https://www.510kdatabase.net/k151013/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Apr 15, 2015
Decision date	Apr 30, 2015
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vitasystems GmbH</b>
Location	Chemnitz, DE
Contact	Michael Rothhaar
510(k) history	3 submissions · 3 cleared · 2010-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151013/> 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 June 3, 2026