

K100383 VITAPHONE. MODEL 100 BTApr 20, 2010
63 days to decisionK100383 · Product code: **DXH** · Cardiovascular
Source: <https://www.510kdatabase.net/k100383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	Feb 16, 2010
Decision date	Apr 20, 2010
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vitasystems GmbH
Location	Chemnitz, DE
Contact	TILO BORCHARDT
510(k) history	3 submissions · 3 cleared · 2010-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100383/> Data sourced from FDA 510(k) public records (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. - Generated June 3, 2026