

K123658 BIOMODULE 3-M1Apr 24, 2013
147 days to decisionK123658 · Product code: **DRX** · CardiovascularSource: <https://www.510kdatabase.net/k123658/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Electrocardiograph (DRX)
Date received	Nov 28, 2012
Decision date	Apr 24, 2013
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zephyr Technology Corporation
Location	Annapolis, MD, US
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Website	http://zephyranywhere.com/
510(k) history	4 submissions · 4 cleared · 2010-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123658/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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