FDA 510(k) Premarket Notification

K123658 BIOMODULE 3-M1

CLEARED

Apr 24, 2013
147 days to decision

K123658 · Product code: **DRX** · Cardiovascular
Source: 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**
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510(k) history	4 submissions · 4 cleared · 2010-2013