

**K133753 MOME ECG CONTINUOUS DETECTION AND
ARRHYTHMIA DETECTOR**Sep 19, 2014
284 days to decisionK133753 · Product code: **QYX** · Cardiovascular
Source: <https://www.510kdatabase.net/k133753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Outpatient Cardiac Telemetry (QYX)
Date received	Dec 9, 2013
Decision date	Sep 19, 2014
Days to decision	284 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infobionic, Inc.
Location	Lowell, MA, US
Contact	CARRIE NEUBERGER
510(k) history	5 submissions · 5 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133753/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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