

K140847 CARDIOSPY ECG HOLTER SYSTEMSDec 5, 2014
246 days to decisionK140847 · Product code: **MLO** · Cardiovascular
Source: <https://www.510kdatabase.net/k140847/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Apr 3, 2014
Decision date	Dec 5, 2014
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Labtech Kft.
Location	Debrecen, HU
Contact	ZSOLT KATONAI
510(k) history	1 submissions · 1 cleared · 2014-2014

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