

K131897 CV3000 HOLTER ANALYSIS SYSTEMNov 26, 2013
154 days to decisionK131897 · Product code: **MLO** · Cardiovascular
Source: <https://www.510kdatabase.net/k131897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	Jun 25, 2013
Decision date	Nov 26, 2013
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vales & Hills Biomedical Tech. , Ltd.
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	2 submissions · 2 cleared · 2013-2017

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